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CLINICAL INVESTIGATION PROGRAM REPORT CONTROL SYMBOL
MED 300(U) DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER
FORT GORDON GA DEPT OF CLINICAL INVESTIGATION

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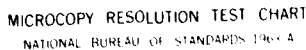
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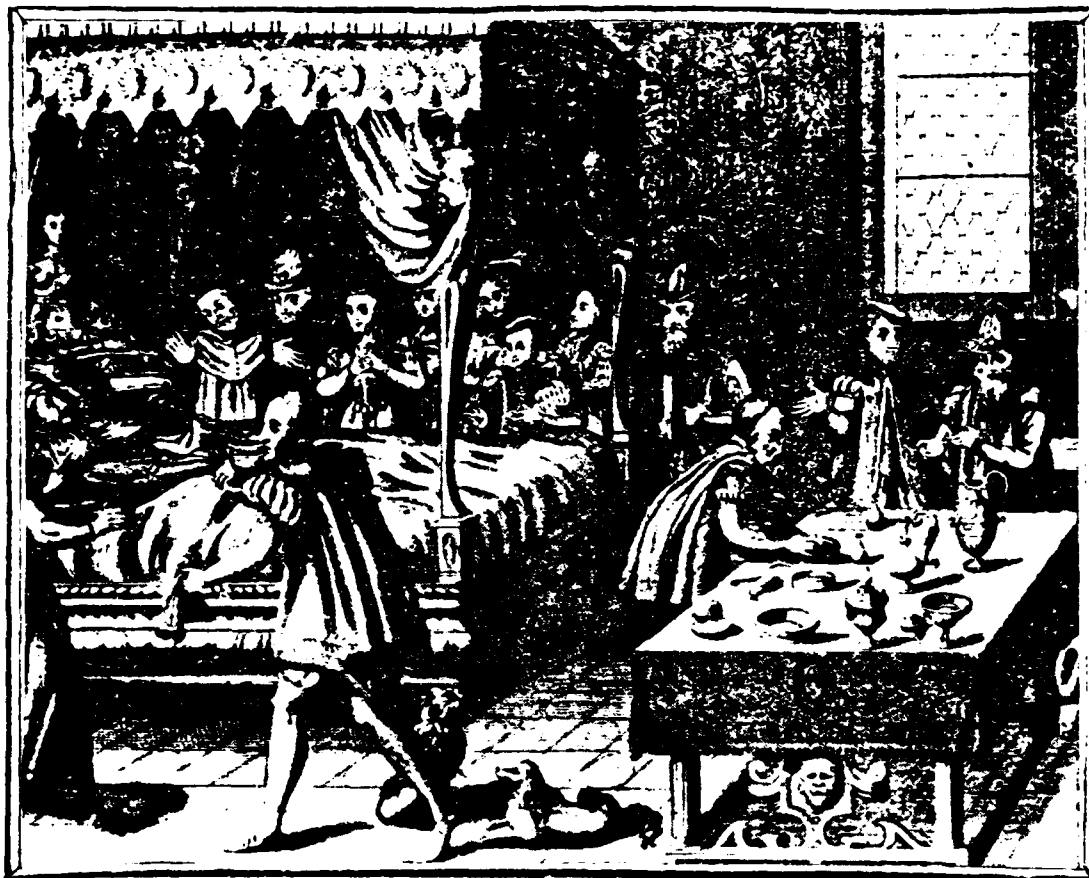




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CLINICAL · INVESTIGATION PROGRAM · REPORT



**DWIGHT DAVID
EISENHOWER**

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ARMY MEDICAL CENTER
FT. GORDON, GEORGIA 30905

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19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Unit Summary; Detail Sheet (Study Objective, Technical Approach, Progress, Status); Publications; Presentations.		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Subject report identifies the research activities conducted by Dwight David Eisenhower Army Medical Center investigators through protocols approved by the Institutional Review Committee for registration with the Department of Clinical Investigation during Fiscal Year 1983, and other known publications and pre- sentations by the Dwight David Eisenhower Army Medical Center professional staff. A detail sheet of each protocol giving the objective, technical approach, and progress is presented.		

FOREWORD

The deathbed scene of Henry II of France depicted on the cover shows the problems and the promises of sixteenth century medicine. The various royal power brokers are standing around wringing their hands, impotent to do anything except to plot some way through the surrounding intrigue. As is evident by the flasks and vials, various nostrums are being pushed. The ubiquitous urine casters are examining the royal urine looking for imbalances in the royal humors and giving erudite philosophical discourses, punctuated by quotes from Galen.

Owing to the gravity of the situation, someone had summoned two of the best medical minds of the century to be in attendance. Andreas Vesalius came from the court of Emperor Charles V where he had gone after a brilliant career as professor of anatomy at Europe's leading medical school in Padua. His book, De Corporis Fabrica, published at age 29, saw man as a fabric of intricately inter-related parts. The extraordinary detail he was able to bring to this revolutionary text was based on the incredible habit that he had for first hand observation of the facts. His teachers and colleagues were quite content to quote Galen and to write commentaries on Galen's writings. Vesalius performed dissections to see what was actually present and to postulate new inter-relationships among systems.

Ambroise Paré, the other giant in attendance, began his career as an army surgeon learning first hand the importance of careful observation and attention to detail. In treating the Duke d'Auret's old gunshot wound, he brought his advanced methods that avoided the established savagery of cauterization and included an entire campaign aimed at healing the man as a part of healing the wound. He provided for clean bedding, for bedside flowers to mask the wound odors, for a machine to simulate rain and to promote sleep, and for bedside violins and comedians to produce merriment. Other accomplishments include an artificial hand, leather trusses for hernias, suturing techniques to reduce scarring, a device for safely cutting bladder stones, establishing the relationship between aortic aneurysms and syphilis, describing prostate hypertrophy as a cause of dysuria, and even a self-administrable douching syringe.

Despite the efforts of these two men, the patient did not survive his mortal wound. As in the real world even today, the best efforts of even the most talented physicians may prove inadequate. However, even now as four centuries ago, we are in better hands with the young Vesalius and Paré's in attendance. These are men who are not satisfied with the accepted wisdom of established medical practice and who seek to further advance that knowledge with controlled studies and insightful observations. Their colleagues and preceptors may be satisfied with the current state of medicine, content to cover over the gaps with extensive quotes from Galen's successors and with more bodily fluids sent for "casting." Both of these activities can have considerable merit when pursued as part of an earnest effort to gain a deeper insight but not when used to wave an Aesculapian wand over ignorance.

Clinical Investigation in the Army continues to be a modest effort to encourage the young Paré s who are using their military experience wisely to make contributions which benefit far more than the limited number of patients they may ever be able to treat as an individual physician. We at DDEAMC are pleased to have the vigorous and sincere support of our Commander, Brigadier General Robert T. Cutting, MC which greatly predates his present assignment. We have been doubly blessed by having Colonel William L. Moore, Jr., MC as our Chief of Professional Services during most of this past year. Like Paré, he is equally at home on the battlefield, in the courts of royalty, and in the practical search for new medical insights. He will be deeply missed as an exemplary role model.

Kent M. Plowman

KENT M. PLOWMAN
Major(P), Medical Corps
Chief, Department of Clinical Investigation



APPROVED	✓
DATE	
BY	
REMARKS	
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UNIT SUMMARY - FISCAL YEAR 1983

A. Objective.

The Department of Clinical Investigation is responsible to the Chief, Professional Services for providing the facilities and atmosphere of inquiry necessary to support and stimulate both basic and clinical medical investigation within DDEAMC.

B. Technical Approach.

All research, investigational, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-38, AR 40-7, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with these applicable regulations.

C. Staffing.

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Plowman, Kent, M.	MAJ(P)	61F00	Chief
Arensman, John B.	MAJ	64A00	Veterinarian
Hannan, Charles J., Jr.	CPT(P)	68Z00	Physiologist/Pharmacologist
Harris, Richard W.	CPT(P)	68J00	Microbiologist
Sherman, Richard A.	CPT	68T9C	Psychobiologist
Losier, Andrew J., Jr.	E7	92B20	NCOIC
Lohr, Edward M.	SP5	92D10	Chem Lab Sp
Dinnigan, Diane	SP4	92B10	Med Lab Sp
Cook, Jeffrey	SP4	91T10	Animal Sp
Gauthier, Pete A.	SP4	92D10	Chem Lab Sp
Lugo, Jesus	SP4	92D10	Chem Lab Sp
Horner, Jack A.	GM13	01301	Asst C, S. Res Histologist
McPherson, James C. III, PhD	GS11	01320	Biochemist
Patterson, Robert A.***	GS9	00181	Psychology Technician
Prior, Robert	GS9	00644	Medical Technologist
Gladney, Diane*	GS7	00404	Biological Lab Technician
Martinez, Rosina	GS6	01087	Editorial Assistant
Bryant, Cheryl	GS4	00312	Clerk Steno
Silas, Bill E.	WG5	07706	Animal Caretaker
Hillis, Minis**	GS2		Clerk (Summer Hire)

*Transferred January 1983

**Three month appointment

***Terminal Leave Pending Medical Retirement

D. Funding.

Type	Fiscal Year 82	Fiscal Year 83
Civilian personnel to include benefits	195,713.00	191,084.00
Consumable supplies	102,881.00	84,395.00
Civilian contracts to include consultants	1,500.00	5,183.00
TDY	10,989.00	3,670.00
Publications	1,934.00	1,145.00
Noninvestment equipment (Minor MEDCASE)	3,144.00	
Other OMA	36,763.00	7,499.00
MEDCASE	179,463.00	134,000.00
Other	3,176.00	2,595.00
Military	279,884.00	305,415.00
Total	815,447.00	729,986.00

E. Progress.

Protocol Disposition FY 83

	<u>Completed</u>	<u>Terminated</u>	<u>Ongoing to FY 84</u>
FY 78	-	-	3
FY 79	-	1	5
FY 80	-	4	2
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Code,

O - Ongoing

C - Completed

T - Terminated

P - Published

PR - Presented

PUBLICATIONS FY 83

DEPARTMENT OF CLINICAL INVESTIGATION

Hannan CJ Jr, Garcia AR. Thyrotropin-releasing hormone (TRH) increases morbidity and mortality in the gerbil stroke model. Neurosci Ltr 1982; 33:299-303. (C)

Horner JA, McPherson JC III, McPherson JC Jr. A comparison of the morphologic effects of the tetronic polyols 1107 and 1508 with Triton WR-1339. Abstract, GA Acad Sci 1983; 41(land2):36. (C)

McPherson JC Jr, McPherson JC III. Experimental hyperlimic agents - Non-toxic alternative agents to Triton WR-1339. Soc Exp Biol Med, SE Sec, Abst 7:14, 1983. (C)

McPherson JC Jr, McPherson JC III. Experimental hyperlimic agents - Non-toxic alternative agents to Triton WR-1339. Proc Soc Exp Biol Med, Abst 172:133, 1983. (C)

McPherson JC Jr, McPherson JC III. A study of the mechanism of the Triton WR-1339 caused delay in gastric emptying - lack of effect of Reglan (R). Georgia Nutrition Council Ann Conf Research Section, Abst, 7:6, 1983. (C)

McPherson JC III, Mahesh VC. Induction of luteinizing hormone, follicle-stimulating hormone surge in the estrogen-primed castrated male rat by progesterones. Biol Reprod 1982; 27:1222-1229. (C)

McPherson JC III, McPherson JC Jr. The failure of metoclopramide to overcome the Triton WR-1339 induced delay of gastric emptying. Abstract, GA Acad Sci 1983; 41(land2):37. (C)

McPherson JC Jr, McPherson JC III. Studies on the mechanism of the delayed gastric emptying in Triton WR-1339 treated rats: lack of effect of Cimetidine. Abstract, GA Acad Sci 1983; 41(land2):37. (C)

Prior R, McPherson JC III, McPherson JC Jr. Tetronic polyols as endogenous hyperlipemic agents. Abstract, GA Acad Sci 1983; 41(land2):36. (C)

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Rissing JP, Buxton TB, Harris RW. Detection of a specific bacterial antigen in urine of rats with Bacteroides fragilis infection. J Lab Clin Med 1983; 102(3):392-399.

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McPherson JC III, McPherson JC Jr. Serum Gastrin Levels in Triton WR-1339 Delayed Gastric Emptying. Endocrinology Abstracts 87:287, 1983.

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DEPARTMENT OF MEDICINE

Johnson WM, Gall EP. Fatal coccidioidomycosis in collagen vascular diseases. J Rheumatol 1983; 10:79-84.

Johnson WM, et al. Respiratory morbidity among workers in an amosite asbestos insulation plant. J Occup Med 1982; 24(12):994-999.

Johnson WM. Selected bladder carcinogens and toxins. In: Environmental and Occupational Medicine, Rom WN, ed. Boston: Little, Brown and Co., 1983:541-546.

Smith L, Wray BB, Stafford CT. Outcome of patients with chronic urticaria and angioedema (Abstract #159). J Allergy Clin Immunol 1983; 71(1)2:128.

Fitz JD, Weeks KD Jr, Duff P. Left ventricular dysfunction in a patient with toxic shock syndrome. Am J Obstet Gynecol Jun 1983; 467-468.

Ansinelli R, Weeks K, Key S. Effect of steroids on postoperative constrictive pericarditis. Am J Cardiol Apr 1983; 1238-1240.

Rathbun JD et al. Impaired hemodynamic function induced by chronic oral propranolol (Abstract). J Am Coll Cardiol 1983; 1(2):667.

ACCEPTED

Guill MA. Cutaneous Mycobacterium szulgai infection. Accepted by Arch Dermatol.

DEPARTMENT OF NURSING

ACCEPTED

Clark FE, Clark MJ. Therapeutic touch: Is there a scientific basis for the practice? Accepted by Nursing Research.

DEPARTMENT OF PATHOLOGY

Hooks TW. Interfacing the ARIA II automated radioimmunoassay analyzer with a desktop computer. Lab Med 1983; 14(9):557-562.

PUBLICATIONS

DEPARTMENT OF PSYCHIATRY AND NEUROLOGY

Shivers WF Jr. A command consultation model for community mental health activities. Military Medicine 1983; 148(2):159-161.

Raskin, Schnapf, Wolf: Computerized tomography in evaluation of Atlantoaxial subluxation in rheumatoid arthritis. J Rheumatol, 10:1, 1983

ACCEPTED

Jensen PS: A study of risk, protective factors, and supportive interventions in chronic airway obstruction. Accepted by Arch Gen Psychiat.

Jensen PS: Barriers to working with impaired trainees: A resident's viewpoint. Accepted by Psychiatric Quarterly.

Jensen PS: The transition to residency seminar. Accepted by Psychiatric Education.

Jensen PS: Case report of conversion catatonia. Indication for hypnosis. (Abst) Accepted by Hospital and Community Psychiatry.

DEPARTMENT OF SURGERY

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DEPARTMENT OF FAMILY PRACTICE

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DEPARTMENT OF MEDICINE

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DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

Broadnax GB: Update on Treatment of PID. Presented to Tennessee Osteopathic Medical Association, Chattanooga, TN, April 1983.

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DEPARTMENT OF PATHOLOGY

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PRESENTATIONS

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DEPARTMENT OF SURGERY

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Bender DR: Computers in Audiology. Presented at US Army Regional Audiology Seminar, Fort Bragg, NC, September 1983.

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Rush L: A new, progressive ambulation program for cardiac patients. Presented at American Physical Therapy Association, Kansas City, MO, June 1983.

Dales R, Eddleman W. Principles of management of concomitant AV injuries of the lower extremity. Presented at Gary P. Wratten Surgical Symposium, Augusta, GA, Mar-Apr 1983.

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Classen J, Davies R. Acute appendicitis: Delay in surgical intervention versus postoperative infectious complications. Presented at Gary P. Wratten Surgical Symposium, Augusta, GA, Mar-Apr 1983.

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PRESENTATIONS

SOCIAL WORK SERVICE

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Platte RJ. Counseling hospitalized patients and their families. Presented to Social Work Staff, Humana Hospital, Augusta, GA, Oct 1982.

Maury JL. Patterns of coping with stages of cancer: The child-patient and his/her family. Presented at Uniformed Services Academy Family Practice, Washington, DC, 26 Apr 1983.

Dalton PH. Role of family advocacy case management team at family advocacy program orientation. Presented to Staff Directors, Commanders, Key NCOs, Ft Gordon, GA, Sep 1983.

Hagen DM. Sexuality and the family - sexual dysfunctioning of the physically disabled. Presented to CSRA Family Counseling Center and National Assn Social Workers, Augusta, GA, Mar 1983.

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Wolf PL. Teaching communication skills to Family Practice residents. Presented at Soc Teachers Family Med, Boston, MA, 10 May 1983.

Wilson TM. Bladder adenocarcinoma in association with pelvic lipomatosis. Presented at Annual Kimbrough Urological Seminar, New Orleans, LA, 28 Nov - 3 Dec 1982.

Parker EO. Low dose Fentanyl: Effects on thiopental requirements and hemodynamic response during induction and intubation. Presented at Annual Meeting Am Soc Anesthesiologists, Las Vegas, NV, 21-27 Oct 1982.

Jennings SA. Preventing wound infection from distant endogenous sources in the rat. Presented at Gary P. Wratten Surgical Symposium, Augusta, GA, 29 Mar - 1 Apr 1983.

Detail Summary Sheet

Date 19 Oct 83	Prot No.: 78-5	Status: Ongoing
Title: A Vascular Occlusion Stroke Model: I. A Technique for Evaluating Therapeutic Approach and Predisposing Factors.		
Start Date: Feb 78	Est Comp Date:	
Principal Investigator(s) Charles J. Hannan, Jr., PhD, CPT, MSC	Facility: DDEAMC	
Dept/Svc: Clinical Investigation	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
Study Objective: To evaluate predisposing factors and experimental therapies in the gerbil model of cerebral ischemic stroke.		

Technical Approach: Temporary surgical occlusion of both common carotid arteries for 40 minutes was employed to produce an experimental model of stroke.

Progress: Preliminary findings indicate a beneficial effect from a superoxide dismutase-polyethylene glycol preparation administered before occlusion. Superoxide dismutase (SOD) is a naturally occurring, ubiquitously distributed enzyme which plays a role in the protection of cells from oxygen toxicity. Free radicals of oxygen may be produced upon the reperfusion of ischemic tissue. SOD has been modified by bonding it to polyethylene glycol in order to increase its half life in plasma. The PEG-SOD prepared had an activity of about 2100 units/ml (assayed by inhibition of xanthine oxidase reduction of cytochrome c according to McCord and Fridovich, JBC 244:6049, 1969). PEG-SOD (10 ul/gm or 20,000 units/kg) was administered intraperitoneally to 20 animals and an equal volume of saline to a group of 13 control animals, 3 hours before occlusion. Mortality figures indicated a beneficial effect of PEG-SOD ($P = 0.0778$ by Chi square). A clearance curve for PEG-SOD indicated plasma SOD activity to be considerably elevated at least 48 hours after injection.

These preliminary results are encouraging for a role of oxygen free radical damage during post ischemic reflow. Further studies to determine the exact time course for the protective effect as well as the role of vitamin E are now being conducted.

Detail Summary Sheet

Date 26 Sep 83 Prot No.: 79-7 Status: Ongoing
 Title: Control of Gonadotropin Secretion in the Male Rat.

Start Date: May 79		Est Comp Date:
Principal Investigator(s) James C. McPherson III, PhD, DAC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators.
Key Words: Gonadotropins Steroids		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the role of estrogens, progestins and androgens either alone or in combination in the regulation of gonadotropin secretion.

Technical Approach: Immature male and female rats and neonatally androgenized female rats are castrated and given replacement steroid therapy beginning immediately and continuing for five days. These animal models are utilized to study the effects of various steroids both individually and in combination on the control of gonadotropin secretion, including the pituitary sensitivity to LHRH, peptide and neurotransmitter roles. Secondary sex organs are removed and weighed as a measure of biological activity of the steroids. Serum and tissue samples are analyzed for a variety of endocrine components including gonadotropins, peptides, steroids and neurotransmitters.

Progress: Neonatally androgenized female rats are being studied to assess the effect of neonatally administered androgens on the control of gonadotropin secretion. This animal model has recently been called the lightly androgenized female rat by some authors. We are currently analyzing the "normal" state of these animals prior to endocrine therapies to invoke normal female reproductive functions in these animals. Current endocrine steroid profiles of these animals indicates low or undetectable levels of Δ^4 -androstenedione, testosterone, estrone, estradiol and progesterone as compared to diestrus day one normal cycling female rats.

Detail Summary Sheet

Date 26 Sep 83 Prot No.: 79-19 Status: Ongoing
 Title: Gastrointestinal Hormones in Non-Ionic Surface Active Agent Induced Delay of Gastric Emptying.

Start Date: Jan 80		Est Comp Date:
Principal Investigator(s) James C. McPherson III, PhD, DAC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators: James C. McPherson, Jr., M.D., Medical College of Georgia
Key words: Gastric emptying Surfactants Gastric secretion		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the effect of non-ionic surface active agents on gastric emptying, voluntary food consumption, body weight and blood chemistries.

Technical Approach: Groups of fasted rats were given non-ionic surface active agents followed 30 minutes later by a commercial rat tube feeding diet. Animals were sacrificed at various times after feeding and gastric emptying compared to control groups. In another series of experiments, rats were injected daily for four days with non-ionic surface active agents. Voluntary food consumption before and during treatment was measured. Twenty-four hours following the last injection, the animals were sacrificed and blood drawn for blood chemistries. In an additional series of experiments the effect of non-ionic surface active agents on gastric secretion is being assessed. Cimetidine, a known gastric secretion inhibitor and metoclopramide, a known agent that stimulates motility of the upper gastrointestinal tract without stimulating gastric secretion, have been utilized to access the actions of these non-ionic surface active agents on delayed gastric emptying. Serum gastrin levels were assayed by radioimmunoassay in fed and non-fed rats given saline or Triton WR-1339 (a non-ionic surface active agent which delays gastric emptying).

Progress: It appears from the studies conducted thus far that the delay in gastric emptying and fluid accumulation in Triton WR-1339-treated rats is not significantly affected by cimetidine. The ratio of the weight of dried recovered diet in the stomach/weight of 5 ml of dried fed diet was 0.467 ± 0.94392 ml in the cimetidine group (p=NS). It also appears that the delay in gastric emptying in Triton-treated animals is probably not due to a decrease in gastric motility since metoclopramide had no significant effect on gastric emptying in Triton-treated rats receiving metoclopramide vs saline. After two hours the ratio of recovered/fed diet was 0.771 ± 0.048 in saline-treated and 0.175 ± 0.104 in metoclopramide-treated rats (p=NS). After 4 hours, the

79-19 Continued

ratios were 0.467 ± 0.136 (saline) and 0.352 ± 0.202 (metoclopramide), $p=NS$. Experiments were designed to assess the effect of Triton WR-1339 on serum gastrin levels as a possible mechanism of action of delayed gastric emptying in these animals. Gastrin levels remained steady in saline non-fed rats. Gastrin was significantly elevated by 5 min in saline fed rats and continued to rise, reaching peak levels between 90 min and 2 hours. Gastrin levels returned to 0 min values by 8 hours in these animals. Serum gastrin levels in Triton non-fed rats had a small but significant rise by 45 min which continued through 8 hours. Gastrin in Triton fed rats was not significantly elevated until 15 min, continued to rise through 80 min and remained elevated through 8 hours. These prolonged elevated gastrin levels in Triton-treated rats. Gastrin release was significantly delayed initially in Triton fed rats. The sustained increased levels of gastrin in Triton fed rats is due to the prolonged gastric distension due to gastric secretion stimulated by Triton. The elevated and prolonged gastrin levels failed to affect the action of Triton on delaying gastric emptying.

Detail Summary Sheet

Date 3 Oct 83 Prot No.: 79-21 Status: Ongoing
 Title: The Experimental Fat Embolism Syndrome: An Electron Microscopic Study of Lung in Three Models.

Start Date: Jun 80		Est Comp Date:
Principal Investigator(s)		Facility:
Jack A. Horner, B.S., DAC		DDEAMC
Dept/Svc:		Associate Investigators:
Clinical Investigation		James C. McPherson III, PhD, DAC
Key Words:		James C. McPherson, Jr., M.D.,
Fat embolism		Medical College of Georgia
Electron Microscopy		
Accumulative MEDCASE	Est Accumulative	Periodic
Cost:	OMA Cost:\$1200	Review Results

Study Objective: Experimental fat embolism syndrome is usually induced by one of five techniques: 1) fracture of the femur of an animal, 2) injection of extracted or homogenized adipose tissue from a same species donor, 3) injections of olive oil or purified triolein, 4) injection of oleic acid, or 5) injection of mineral oil (all injections given intravenously). In this study the similarity and differences, if any, in these last three techniques (olive oil, oleic acid, and mineral oil) will be investigated.

Technical Approach: Fat embolism is a major (although frequently undiagnosed unless severe) complication in patients with fractures of the long bones and/or severe trauma. The etiological mechanism of this syndrome is still unsettled. The two mechanisms most widely accepted are: 1) fat from the bone marrow of fractured bones or traumatized adipose tissue enter into small broken veins and travel to the lung where blockage of the capillaries and arterioles occur, and 2) after trauma, the circulating lipoproteins in blood coalesce to form globules of fat large enough to block the capillaries of the lung. In addition, once the fat has blocked a capillary or arteriole, the pathogenic events which follow are unclear. The major effect may be a simple blockage, but some investigators believe the most harmful effects result from the release of free fatty acids from the "trapped" fat globules in the lung. This study will attempt to establish the differences which could be important in the clinical syndrome by examining a mineral oil model (pure blockage with no possible release of free fatty acid from the globules), oleic acid (effect of free fatty acid only), and olive oil (fat capable of hydrolysis to yield free fatty acids). This study may add to our basic understanding of the events in the pathogenesis of the clinical fat embolism syndrome and suggest the basis of new methods of treatment.

Progress: In order to preserve the pulmonary tissue in the most artefact free manner, improvements must be made in fixation techniques. An apparatus is

79-21 Continued

under construction to permit carefully controlled osmium vapor fixation. Preliminary results indicate a substantial improvement. The timely conduct of this study has been hampered by the lack of technical support for the past nine months. This problem is expected to be corrected within the next 60 days with the hiring of an EM technician. At that time the study will resume.

Detail Summary Sheet

Date 4 Oct 83 Prot No.: 79-23 Status: Ongoing
 Title: Examination of Multi-Microbial Abscesses in Animal Models: II.
 Morphological and Bacteriological Comparison.

Start Date: Oct 82	Est Comp Date:
Principal Investigator(s) Richard W. Harris, CPT, MSC	Facility: DOEAMC
Dept/Svc: Clinical Investigation	Associate Investigators: Jack A. Horner, DAC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: To examine bacteriological and physiological parameters of an animal abscess model involving continuous sampling.

Technical Approach: To examine the morphological definition of abscesses by scanning electron microscopy during the development of the abscess.

Progress: Initial observations have been made to compare development of sub-cutaneous and intraperitoneal responses to implanted perforated plastic capsules. Measurements include pH, white cell counts, white cell differential, glucose and protein. Initial comparisons were difficult due to bleeding into i.p. capsules. Capsules are now being implanted and compared at a later stage of development.

Detail Summary Sheet

Date 4 Oct 83 Prot No.: 79-35 Status: Terminated
 Title: Rapid Diagnosis of Viral Respiratory Infection.

Start Date: Feb 80	Est Comp Date:
Principal Investigator(s) Richard W. Harris, CPT, MSC	Facility: DOEAMC
Dept/Svc: Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To determine feasibility of rapid viral diagnosis in patients with ARD by methods of direct electron microscopy and enzyme-linked immunoabsorbant assay.

Technical Approach: Throat swabs from patients with ARD are inoculated into holding medium, split, cultured, processed for EM and ELISA.

Progress: Due to the PCS of the previous principal investigator, LTC Haburchak, this protocol has been terminated.

Detail Summary Sheet

Date 7 Oct 83 Prot No.: 80-18 Status: Terminated
 Title: Conduit From Thoracic Duct to Esophagus: Application of New Surgical Procedure.

Start Date: Mar 80	Est Comp Date:
Principal Investigator(s) J. Bruce Arensman, DVM, MAJ, VC	Facility: DOEAMC
Dept/Svc:	Associate Investigators: A.L. Humphries, M.D., Medical College of Georgia
Clinical Investigation	
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To prove the efficacy of the proposed surgical procedure and to make a practical application of it. The flow of lymph into the gastrointestinal tract will result in destruction of lymphocytes and reduction of serum IgG and IgA levels to create a form of immunosuppression.

Technical Approach: Using the left jugular vein and right carotid artery, an A-V fistula is formed with the carotid artery routed through the esophageal musculature in proximity to the submucosa. In a second operation, two weeks later, the carotid and brachiocephalic vein are ligated and the lumen of the carotid opened into the esophageal lumen. Lymph can then flow from the thoracic duct through the jugular, through the transplanted carotid, into the esophagus.

Progress: No activity has occurred on this protocol during this fiscal year. All work is being done at the Medical College of Georgia and the VA. Recommend termination as a DOEAMC protocol.

Detail Summary Sheet

Date 3 Oct 83 Prot No.: 80-28 Status: Ongoing
 Title: Antimicrobial Therapy in an Animal Abscess Model.

Start Date, Jun 81	Est Comp Date:
Principal Investigator(s) Richard W. Harris, CPT, MSC	Facility: DOEAMC
Dept/Svc:	Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC Richard W. Harris, CPT, MSC William L. Moore, COL, MC
Clinical Investigation/Medicine	
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: To develop an appropriate methodology for examination of effects of antibiotics on monomicrobial and polymicrobial abscesses.

Technical Approach: In order to produce an encapsulated virulent strain, all stock organisms studied will be passed through a mouse or rat by s.c. injection with soft agar. The aspirated organism will then be used for rabbit inoculation.

Progress: The antimicrobial activity of moxalactam was examined over time against Bacteroides fragilis and Escherichia coli individually and in combination in an intraperitoneal tissue capsule animal model. Moxalactam serum and capsular aspirate concentrations along with capsular bacterial counts (log mean \pm SD) were measured intermittently during 10 days of moxalactam therapy given at 40 mg/kg/day as 3 equal i.m. 8 hourly doses. Mean capsular moxalactam concentrations during samplings on days 3, 7, and 10 were 1.8 μ g/ml for B. fragilis, 0.7 μ g/ml for E. coli, < 0.5 μ g/ml for polymicrobial infection and 3.4 μ g/ml in uninoculated controls. Mean peak serum concentration was 32.8 μ g/ml. Capsular colony counts in monomicrobial infections decreased from 7.7 ± 0.7 cfu to 5.5 ± 0.7 cfu for B. fragilis and from 7.6 ± 0.2 cfu to 3.6 ± 1.0 cfu for E. coli. Capsular colony counts in polymicrobial infections decreased from 7.9 ± 0.2 cfu to 6.0 ± 0.6 cfu for B. fragilis and 7.6 ± 0.2 cfu to 4.0 ± 1.4 cfu for E. coli. Moxalactam concentrations necessary to eliminate viable bacteria in both monomicrobial and polymicrobial capsules were not achieved.

An investigation is now under way to examine a higher moxalactam dosing schedule of 100 mg/kg/day and in comparison to other new cephalosporin antibiotics.

Detail Summary Sheet

Date 18 Oct 83		Prot No.: 80-29		Status: Ongoing	
Title: Differentiation of Bacteria <u>in vivo</u> by Gas Liquid Chromatography.					
Start Date: Nov 81			Est Comp Date:		
Principal Investigator(s)			Facility:		
Richard W. Harris, CPT, MSC			DOEAMC		
Dept/Svc:			Associate Investigators:		
Clinical Investigation			J. Bruce Arensman, DVM, MAJ, VC		
Key Words:			William L. Moore, Jr., M.D., COL, MC		
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To determine patterns of metabolite production by electron capture gas chromatography in an abscess animal model.					

Technical Approach: Exudate from the rabbit model will be used to compare monomicrobial abscesses. Organisms will be implanted with soft agar and exudate will be examined upon abscess formation. Serum will be drawn for determination of metabolites.

Progress: This protocol will be initiated when technical support can be allocated for the gas chromatography analysis.

Detail Summary Sheet

Date 26 Sep 83 Prot No.: 81-16 Status: Ongoing
 Title: Correlations Between Amount of Information Feedback and Success of Biofeedback Treatments.

Start Date: Feb 81	Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation Psychology Service	Associate Investigators: Ralph Bruno, PhD, CPT, MSC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Mar 83 Review Results Continue

Study Objective: To determine whether increasing the amount of information about muscle tension given to patients with muscular control problems will shorten treatment times and increase the overall effectiveness of the treatment.

Technical Approach: For patients with bruxism, half receive muscle tension feedback from the masseter muscle, weekly in the laboratory, and wear a masseter tension monitor nightly at home. The other half does the same with the addition of receiving feedback from the night monitor when they begin tensing their jaws. For patients with subluxation of the patella, muscle tension in the vastus medialis and lateralis will be recorded. Half will receive a combined feedback proportional to their relative tension and half will receive two independent signals juxtaposed in various ways indicating both relative and absolute muscle tension.

Progress: Subjects enrolled through FY 82 - 32; FY 83 - 61. The laboratory portion has been completed. We are in the process of evaluating the data from patients with pain due to bruxism. The home portion (using portable muscle tension feedback units) will begin as soon as our units are modified to accept counters.

Detail Summary Sheet

Date 27 Sep 83 Prot No.: 81-17 Status: Ongoing
 Title: Intrasession Psychophysiologic Arousal Correlates of Psychotherapy and Behavior Treatment.

Start Date: Feb 81	Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation, Psychiatry / Neuro	Associate Investigators: Ralph Bruno, PhD, CPT, MSC William G. Bissell, M.D., LTC, MC
Key Words: Arousal Psychotherapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Mar 83 Review Results Continue

Study Objective: To monitor patterns of arousal among patients undergoing group psychotherapy, individual psychotherapy, or individual behavior therapy to detect correlations between therapeutic work/intervention and arousal (as reflected by psychophysiologic parameters) during a session.

Technical Approach: Patients in the above settings will be instrumented appropriately so that various psychophysiologic parameters indicative of arousal (heart rate, respiration rate, number of GSR's, muscle tension, peripheral vasoconstriction, etc.) can be continuously monitored throughout a session. All verbal interactions will be recorded on a second by second basis on the physiologic data tape to permit correlation between arousal and therapy.

Progress: Not in progress due to lack of technical support.

Detail Summary Sheet

Date 27 Sep 83 Prot No.: 81-18 Status: Ongoing
 Title: Environmental Stress and Electromyographic Correlates of Chronic Posterior Trunk Muscle Pain.

Start Date: Feb 81		Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, OPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation Psychology, Orthopedics		Associate Investigators: Jack K. Tippens, M.D., COL, MC
Key Words: Low back pain Upper back pain Muscle tension		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 83 Review Results Continue

Study Objective: To record those muscles in the posterior trunk of patients with lower and upper back, shoulder, or neck pain related to abnormal muscle tension in order to ascertain relationships between stress, pain, and tension as well as evaluate the effectiveness of muscular relaxation training as a treatment for these problems. The relative effectiveness of these treatments for pain in the above areas with and without underlying muscle tension problems will be evaluated.

Technical Approach: Recordings of muscle tension; objective psychosomatic measures of stress, anxiety, functional locus and other factors; discomfort logs; and other measures will be made before, during and after muscle relaxation treatments of individuals with the problems described above. These progressive measures will be compared with identical measures made of individuals with: 1) musculoskeletal related pain in other areas; 2) high anxiety but no musculoskeletal pain; and 3) posterior trunk pain but no muscle tension problem. A second phase of the study will consist of continuous muscle tension recordings made throughout the day using wearable EMG recorders. These measures will be related to a continuously tape recorded log of environmental loci and stresses.

Progress: The effectiveness of a muscle tension profile for patients with low back pain of various origins has been developed and tested. A normal data base for several age-sex groups commonly found in Army low back pain clinics has been developed. Further elucidation of profiles is awaiting arrival of a videothermography unit due in October. The study has been broadened to include studies of soldiers at risk for developing back pain of muscle tension origin during field exercises.

Subjects enrolled through FY 82 - 40; FY 83 - 73.

Detail Summary Sheet

Date 27 Sep 83 Prot No.: 81-19 Status: Ongoing
Title: Investigations of Chronic Phantom Pain.

Start Date: Feb 81	Est Comp Date: Jan 85
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC	Facility: DDEAMC
Dept/Svc:	Associate Investigators: Norman Gall, M.D., AMVAH San Antonio
Clinical Investigation	Roberto H. Barja, M.D., COL, MC
Key Words: Phantom pain	Jeff Grant, PhD, VA, Augusta
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Mar 83 Review Results Continue

Study Objective: 1) Develop an understanding of the underlying causes of phantom pain; 2) determine the extent of phantom pain among the amputee population; 3) develop comparative differential profiles of amputees with and without phantom pain; and 4) evaluate new treatments of phantom pain.

Technical Approach: All service connected amputees who can be located receive a mail survey requesting information about their amputation, stump pain, phantom pain, etc. All service connected veterans living near DDEAMC and all amputees treated at DDEAMC or VAMC Augusta are asked to participate in a psychometric and psychophysiologic profile. All phantom pain patients seen at any participating center receive the same profile as part of the pretreatment workup.

Progress: The military and civilian surveys have been completed and are in various stages of publication ranging from published to accepted, and in preparation. An article on suggested guidelines for treatment of phantom limb pain has been published. We are cooperating with the spinal cord unit at the VA for evaluation of phantom body pain. We are holding off evaluating more amputees at DDEAMC until the videothermography and automatic sphygmomanometer systems arrive in early October.

Detail Summary Sheet

Date 26 Sep 83		Prot No.: 81-42		Status: Ongoing	
Title: Experimental Fat Embolism Syndrome: Basic Studies and Evaluation of Currently Available Therapies and New Agents.					
Start Date: Oct 81			Est Comp Date:		
Principal Investigator(s) James C. McPherson III, PhD, DAC			Facility: DDEAMC		
Dept/Svc: Clinical Investigation			Associate Investigators: Jack A. Horner, DAC J. Bruce Arensman, DVM, MAJ, VC Robert Prior, DAC		
Key Words: Fat embolism Surfactants					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: Evaluation of current therapies and new therapies for treatment of fat embolism syndrome in an experimental animal model.

Technical Approach: This project is being investigated in five phases. Metabolic evaluation of the non-ionic surface active agents is being conducted using an eleven parameter profile developed to screen these agents and analyzed by a Technicon RA-1000 (a mini-SMA instrument). The profile includes cholesterol, triglyceride, glucose, urea N, creatinine, uric acid, bilirubin, LDH, SGOT, CPK and ALT. Electrolyte blood cell indices and other parameters are under investigation or consideration.

Progress: The initial metabolic evaluation of the non-ionic surface active agents is nearing completion. These agents may be divided into three classes of compounds: non-hyperlipemic agents, hyperlipemic agents of short duration, and hyperlipemic agents of long duration (24 hours or longer). It appears that some of these agents are suitable alternative agents to Triton WR-1339 as an endogenous hyperlipemic agent. These agents, in contrast to Triton appear to be both hyperlipemic agents and non-hemolytic. These agents may be useful in evaluating anticholesterolic drugs. These pluronic polyols may be useful as non-toxic alternate agents to Triton in studies where endogenous hyperlipemic agents are needed.

Detail Summary Sheet

Date 27 Sep 83	Prot No.: 82-20	Status: Ongoing
Title: Correlations Between Extent of Patient Involvement and Effectiveness of Published Behavioral Treatments of Hypertension.		
Start Date: Nov 81	Est Comp Date:	
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC	Facility: DDEAMC	
Dept/Svc: Clinical Investigation	Associate Investigators:	
Key Words: Patient involvement Hypertension Behavioral treatment		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether the extent of patient in behavioral treatment of hypertension affects treatment success.

Technical Approach: The methods and results sections of all published articles on behavioral treatment of hypertension containing sufficient detail to permit analysis are sorted into "blind" booklets for rating. Physician and PhD groups are asked to "blind" rate each method and result section without knowing which are related to each other.

Progress: Raters are in the process of going through the booklets. The study has been extended to include behavioral treatments of muscle tension headaches.

Detail Summary Sheet

Date 27 Sep 83 Prot No.: 82-43 Status: Ongoing
 Title: Development of an Animal Model of Phantom Pain.

Start Date:	Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC Charles J. Hannan, Jr, PhD, CPT, MSC Mrs. Crystal Sherman, M.S.
Key Words: Phantom pain Animal model Rat	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results
Study Objective: To develop an animal model of phantom pain.	

Technical Approach: Rats are trained to respond to gentle, harmless, shocks by pressing different levers depending on where along the foreleg the shock is given in order to receive a milk reward. After training is successful, the foreleg is amputated by a combined veterinary-orthopedic surgery team while the animal is under anesthesia. Following recovery, the shocks are presented to the remaining portion of the foreleg. The number of responses to stimulation of areas no longer present are compared with the previous number of incorrect responses.

Progress: This study has not been started due to the lack of technical support availability.

Detail Summary Sheet

Date 19 Oct 83		Prot No.: 82-44	Status: Ongoing
Title: Biochemistry of Acute Psychosis.			
Start Date: Jun 82		Est Comp Date:	
Principal Investigator(s)		Facility:	
Charles J. Hannan, Jr., PhD, CPT, MSC		DDEAMC	
Dept/Svc:		Associate Investigators:	
Clinical Investigation, Psychiatry		William F. Shivers, Jr., M.D., LTC, MC	
Key Words:		G. Franklin Carl, PhD, VAMC	
		Alan Boulton, DSc, Univ Hospital	
		Saskatoon, Canada	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results	

Study Objective: Through a multicenter cooperative effort, biochemical measurements will be made on blood fractions obtained from DDEAMC psychiatric patients, and these results will be correlated with symptomatology.

Technical Approach: Study design will be composed of four parts: a) psychiatric diagnostic criteria and coordination of referral sources for inclusion of subjects and controls; b) collection, fractionation and distribution of blood products to investigators; c) biochemical determination on blood fractions by investigators; d) collection and analysis of data considering diagnostic information and two month followup of subjects.

Progress: To date there have been a total of 12 patients, 12 normal controls and 11 patient controls entered on this protocol. Diagnostic detailed information and followup has not been completed. Some samples of blood products to participating research collaborators were ruined in shipment due to carrier errors. Results of the COMT determination on some of the subjects has been completed and is summarized as follows:

Three groups of subjects (acute patients with matched patient controls and normal controls) were examined for COMT activity in two red blood cell (RBC) preparations (soluble and soluble plus membrane fractions). Dopamine was used as substrate, with SAM the co-substrate, in concentrations producing maximal activity. Dithiothreitol (DTT) was added to some assays. Products of the reaction were quantitated by HPLC with electrochemical detection using an internal standard technique. Soluble COMT generated 3-methoxytyramine (3MT) or 4-O-methyldopamine (4MT) from the substrate at rates illustrated in the table below:

GROUP	n	No additions*		DTT*	
		3MT**	4MT**	3MT	4MT
Acute Patient	6	10.03 ± 4.2	.68 ± .37	24.02 ± 12.1	4.91 ± 2.9
Patient Control	5	9.18 ± 3.9	.99 ± .26	29.72 ± 20.5	5.51 ± 3.0
Normal Control	6	4.66 ± 1.7	.43 ± .31	28.79 ± 14.2	9.21 ± 5.7

*Activity as ng product/min/ml packed RBC (mean ± SD)

**Significant difference among groups (P<.05) ANOVA

82-44 Continued

Significant differences among groups ($p < .05$) when DTT was not in the assay mixture is attributed to the normal control group being different from both acute patient (non-medicated) and patient control (neuroleptic medication >2 weeks) groups. The soluble plus membrane COMT preparation also had significant ($p < .05$) differences among groups in the absence of DTT. The approximately 3 fold higher activity of COMT in the presence of DTT abolished the difference among groups, although maximum enzyme activity may be sought in an attempt at normalizing results. Many published reports include DTT in the COMT assay and this may explain some inconsistent results among different investigators. In summary, the COMT activity was demonstrated to be different between normals and psychotic patients, independent of neuroleptic medication.

Detail Summary Sheet

Date 4 Oct 83 Prot No.: 82-47 Status: Completed
 Title: Detection of Bacteroides fragilis Antigen in Human Serum and Urine by Immunoassay.

Start Date: Oct 82	Est Comp Date: Sep 83
Principal Investigator(s) Richard W. Harris, CPT, MSC	Facility: DOEAMC
Dept/Svc: Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To determine if Bacteroides fragilis antigen(s) can be detected by immunoassay in patients with documented B. fragilis infections. Urine and serum will be sampled for antigen.

Technical Approach: Patients that are culture positive for B. fragilis will be asked to participate in the study. One serum and three urines will be obtained over a one-week period. 24-hour urines will be obtained. Urine will be dialyzed and analyzed by an indirect immunosorbent assay specific for B. fragilis outer membranes.

Progress: Total of 28 subjects enrolled. Urine was collected from normal subjects, 22 Enterobacteriaceae bacteremia patients, six non-bacteremic Bacteroides fragilis infections and nine Bacteroides fragilis bacteremia patients and analyzed with an indirect immunosorbent assay specific for B. fragilis outer membranes. Three of six non-bacteremic patients and eight of nine B. fragilis bacteremia patients yielded values > 2 standard deviations from controls. None of the 22 patients with Enterobacteriaceae bacteremia were falsely positive. The results have been submitted to the Journal of Infectious Diseases for consideration for publication entitled "Detection of Specific Bacterial Antigen in Urine of Patients with Bacteroides fragilis Infection."

Detail Summary Sheet

Date 27 Sep 83 Prot No.: 83-8 Status: Ongoing
 Title: Effects of the Psychophysiologic Recording Environment on Stress Labile Physiologic Systems.

Start Date:	Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators: Jack A. Horner, B.S., DAC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: 1) To determine the placebo value of an electronic device used with several physiologic dysfunctions in which stress is the major independent variable underlying temporal patterns of severity. 2) To evaluate habituation to the environment through repeated recording of the parameters over time.

Technical Approach: Forty, newly diagnosed, unmedicated borderline hypertensives (BPs in range of 140/90 - 160/110) and 40 chronic tension headache patients will participate in the study. All participants will be basically free of other disorders at the start of the study and will be dropped from the study if need for medication occurs, or other problems develop.

Progress: This study has not started; we are awaiting construction and purchase of equipment, and technical support availability.

Detail Summary Sheet

Date 19 Oct 83	Prot No.: 83-34	Status: Ongoing
Title: Visualization of Imipramine Binding Sites on Red Blood Cells and Platelets.		
Start Date: Oct 83	Est Comp Date: Jul 84	
Principal Investigator(s) Charles J. Hannan, Jr., PhD, CPT, MSC Jack A. Horner, DAC	Facility: DDEAMC	
Dept/Svc: Clinical Investigation	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Imipramine binding is known to correlate with serotonin uptake in platelets. Serotonin uptake, and therefore, imipramine binding, have been demonstrated to be abnormal in various psychiatric diseases. Our goal is to visualize these binding sites using a radioactive tracer to expose fine photographic emulsion and view their spatial arrangement under the scanning electron microscope (SEM).

Technical Approach: This study will be conducted in two parts. Part one will involve the perfection of the SEM autoradiographic techniques using human blood obtained as excess from the blood bank. Part two will involve the application of these techniques to a patient population. The patients utilized will be those already consenting to participate in DDEAMC Protocol 82-44 "Biochemistry of Acute Psychosis." No additional blood will be drawn since that presently obtained under the protocol is sufficient in quantity to supply the few drops needed for this further test. Protocol 82-44 includes a suitable control population which will also serve for this study.

The techniques to be established in part one will basically be modified from the work of Weiss (1980). The primary concern will be to determine a processing regimen which does not remove the bound (^3H)-imipramine until after the autoradiogram is exposed. The general scheme will entail incubation of the RBC's and/or platelets with (^3H)-imipramine, attachment of the cells/platelets to glass cover slips, fixation in glutaraldehyde and osmium tetroxide, deposition of Ilford L-4 Nuclear Track Emulsion, exposure, development, photographic fixation, dehydration, critical point drying and subsequent examination in the scanning electron microscope.

Progress: Final approval to use radioactive isotopes was received 2 Sep 83 and no further action was taken for the month of September.

Detail Summary Sheet

Date 28 Sep 83 Prot No.: 83-37 Status: Ongoing
 Title: Determination of Glomerular and Nonglomerular Bleeding by Examination of RBC's in Urine Using Scanning Electron Microscope (SEM).

Start Date:	Est Comp Date:
Principal Investigator(s) Jack A. Horner, DAC James A. Hasbargen, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: It has recently been suggested that red blood cells (RBC) from glomerular causes appear different than RBC from nonglomerular causes. Our goal is twofold: a) to insure the differences are not secondary to osmotic or fixation artifacts, and b) to quantitate and confirm the prior observations.

Technical Approach: This study consists of two parts, a study of urine bound red blood cell (RBC) morphological changes as a result of urine parameters (e.g., holding time, pH, osmolarity, etc.), and a characterization of RBC morphology in urine from patients with hematuria both with and without glomerular bleeding. In the first part, normal peripheral blood is placed in urines of varying pH, osmolarity, etc for varying times. The samples are then spun down, fixed in glutaraldehyde, dehydrated, filtered onto nucleopore 0.2μ filters, critical point dried, gold sputtered, and examined in the scanning electron microscope. A minimum of 100 RBC's from each sample will be examined, then morphology noted, and representative cells photographed to determine the effect of urine parameters on RBC morphology. In the second part the same processing regimen is employed on patient urine samples and the resultant RBC morphology recorded.

Progress: The first part of the study has been completed using urines of varying Ph's and osmolarities ranging from under 200 milliosmoles to over 1200 milliosmoles. Holding times of 30 minutes to 72 ohms were employed. The only notable morphological change which could be determined was the frequency of erythrocyte crenation. With osmolarities less than approximately 380 milliosmoles crenation was the predominant case. Whereas, at higher osmolarities crenation was only occasionally observed. In no instance was the unique "doughnut" morphology observed with glomerular bleeding. Part two of this study is just beginning and will progress as suitable patient samples are available.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 83-32 Status: Ongoing
 Title: Mandibular Lingual Vertical Releasing Incisions.

Start Date: Aug 83	Est Comp Date: May 84	
Principal Investigator(s) Thomas J. Lynch, MAJ(P), DC	Facility: DDEAMC	
Dept/Svc: Dental Activity	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Compare the healing and post-operative sequelae of two different types of incisions used in periodontal surgery.

Technical Approach: Each patient in the study will have each of the two types of incisions performed in his mouth, one on each side of the mandible. Progress of healing will be followed with a symptom data log and clinical photographs.

Progress: Thus far only one patient has undergone surgical therapy as a part of this study.

Detail Summary Sheet

Date 30 Sep 83 Prot No.: 81-40 Status: Completed

Title: The Assessment of Improved Physiologic Function With a Short-Term Exercise Program in Mildly to Moderately Obese People.

Start Date: Oct 82	Est Comp Date:
Principal Investigator(s) Jeannette South-Paul, CPT, MC	Facility: DDEAMC
Dept/Svc: Family Practice	Associate Investigators: Michael Tenholder, M.D., LTC, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Nov 82 Review Results Continue

Study Objective: To assess whether there is a significant improvement in cardiovascular and pulmonary parameters, with a short-term exercise program in young people (ages 20-40) who are mildly to moderately obese (10-30% above ideal body weight).

Technical Approach: This project involved a graded exercise test during which pulmonary and cardiovascular parameters were monitored. The patient was then placed on either a diet program alone or on a program of both diet and exercise. He/she was also asked to attend weekly nutrition classes. Eight to 12 weeks after beginning the program, the participant was retested to compare pre- and post-study parameters.

Progress: The project was completed in February 1983. No differences in heart rate or tidal volume could be demonstrated between the two groups before and after completion of the program. The exercise, however, was able to complete more work before reaching anaerobic threshold, improve their oxygen consumption and increase their cardiorespiratory fitness classification significantly more than the diet only group. Exercise, therefore, when used in conjunction with a diet regimen was found to result in significant greater fitness than diet alone in moderately obese people.

Research Award for Best Military Application sponsored by Burroughs-Wellcome presented at Uniformed Services Academy of Family Practice, Washington, DC, 28 April 1983.

Detail Summary Sheet

Date 27 Sep 83 Prot No.: 82-48 Status: Terminated
 Title: Training Laboratory for Selected Procedure in Emergency Medicine for Family Practice Residents.

Start Date: Aug 82	Est Comp Date:
Principal Investigator(s) Gerhard J. Hinnen, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Family Practice Clinical Investigation	Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC
Key Words:	
Accumulative MEDCASE Cost,	Est Accumulative OMA Cost,
	Periodic Review Results

Study Objective: To train Family Practice residents in certain emergency techniques and skills. These include procedures such as tracheostomy, chest tube placement, arterial line placement, venous cutdown, peritoneal lavage, and other procedures a resident may request.

Technical Approach: Using animal models, under general anesthesia, the above procedures are demonstrated by Dr. Arensman and then performed by the residents. All procedures conform to published guidelines and have been approved by the Animal Use and Institutional Review Committees.

Progress: Three residents performed the rotation in the past, and found it worthwhile. None have requested it for this academic year. Therefore, the study may be terminated.

Detail Summary Sheet

Date: 30 Sep 83	Prot No.: 82-53	Status: Ongoing
Title: Hospital Hypertension Study Lopressor ^R (Metoprolol Tartrate) Diuretic/ Beta-Blocker Therapy-Protocol 20.		
Start Date: Nov 82	Est Comp Date:	
Principal Investigator(s)	Facility:	
Jeannette E. South-Paul, M.D., CPT, MC	DDEAMC	
Dept/Svc:	Associate Investigators:	
Family Practice	Family Practice Staff	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the efficacy and tolerability of Lopressor^R (Metoprolol tartrate) when used in combination with a diuretic in the treatment of hypertension.

Technical Approach: Patient selection includes outpatients of either sex with a sitting diastolic blood pressure of 95 to 114 mmHg (inclusive). Patients may be untreated hypertensives or previously treated who have not been on antihypertensives for at least two weeks before entering study. No patient will have antihypertensives discontinued for the purpose of being included in the study. Patients with sinus bradycardia, heart block greater than first degree, cardiogenic shock, or overt heart failure should be excluded from the selection. All patients must be treated in strict conformity with the attached package inserts.

Progress: No enrollments to date on this study.

Detail Summary Sheet

Date 27 Sep 83		Prot No.: 82-56		Status: Ongoing	
Title: Sexual Education Inventory.					
Start Date: Oct 82			Est Comp Date:		
Principal Investigator(s) Gary N. Matteson, M.D., CPT, MC			Facility: DDEAMC		
Dept/Svc: Family Practice			Associate Investigators: Robert Armstrong, M.D., CPT(P), MC Michael Kimes, M.D., MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To develop a tool to measure the adequacy of a physician's education in the area of sexual problems.					

Technical Approach: 1) To develop a questionnaire to determine what education background physicians have in sexual education; 2) determine the prevalence of sexual dysfunctions seen in a Family Practice Clinic; 3) to study the ways physicians deal with patients with sexual dysfunction; 4) to correlate the educational background of the physicians as ascertained on the questionnaire with the reported prevalence of sexual dysfunction seen by the physician.

Progress: 1) Study of this aspect completed; data has been collected on 2), 3) and 4) - currently undergoing computer analysis.

Detail Summary Sheet

Date 27 Sep 83 Prot No.: 83-4 Status: Terminated

Title: The Relationship Between Maternal and Paternal Anthropometry and Resultant Rate of Cephalo-Pelvic Dysproportion.

Start Date: Nov 82		Est Comp Date:
Principal Investigator(s) Weston J. Welker, M.D., CPT, MC		Facility: DDEAMC
Dept/Svc: Family Practice		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the relationship, in a term uncomplicated gestation, between the body sizes of both parents, the size of the baby, and the resultant frequency of Cephalo-Pelvic Dysproportion (CPD).

Technical Approach:

Progress: Principal investigator transferred; no final report submitted.

Detail Summary Sheet

Date 27 Sep 83 Prot No.: 83-7 Status: Ongoing
 Title: Behavioral Science in Military Family Practice Programs, What Do Patients Feel is Relevant?

Start Date: Dec 82	Est Comp Date:
Principal Investigator(s) Robert D. Armstrong, M.D., CPT, MC	Facility: DDEAMC
Dept/Svc: Family Practice	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To determine how much involvement in common psychosocial problems patients of DDEAMC Family Practice Clinic desire of their family - tors. To investigate some variables associated with patient's desire for physician involvement.

Technical Approach: An anonymous questionnaire consisting of approximately 70 items will be distributed to patients in the Family Practice Clinic. Boxes will be located in several prominent places in the clinic for patients to return the completed forms.

Progress: Questionnaire has been distributed, data has been extracted and preliminary statistical work done. Preparation of the paper awaits completion of cluster analysis by consultant.

Detail Summary Sheet

Date 27 Sep 83	Prot No.: 83-18	Status: Terminated
Title: Personality Type as a Predictor of Satisfaction in the Doctor-Patient Relationship.		
Start Date: Feb 83	Est Comp Date:	
Principal Investigator(s)	Facility:	
Kenneth J. Franklin, M.D., CPT, MC	DOEAMC	
Dept/Svc:	Associate Investigators:	
Family Practice		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To test the hypothesis that personality types of doctor and patient can be used to predict the satisfaction that both will have with the doctor-patient relationship.

Technical Approach: Questionnaires will be completed by Family Practice physicians and by patients. Data will be summarized and tabulated using computer programs. Statistical significance between scores on the satisfaction questionnaires and individual type letters will be measured using the student's t-test.

Progress: Further investigation of existing research and similar studies showed the sample size and absolute difference in responses required to obtain statistically significant results were practically impossible to obtain. Also, no modification of the study design could be found to reduce this obstacle. Study terminated.

Detail Summary Sheet

Date 30 Sep 83 Prot No., 83-36 Status: Ongoing
 Title: The Interrelationship of Pregnancy and Fitness.

Start Date:		Est Comp Date:
Principal Investigator(s)		Facility:
Jeannette E. South-Paul, M.D., CPT, MC		DDEAMC
Dept/Svc:		Associate Investigators:
Family Practice		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To determine whether pregnancy causes a decrease in physical fitness as measured by maximum oxygen consumption between the second and third trimesters; and 2) to assess whether the maintenance of a regular exercise program during the second half of pregnancy will affect fitness and the outcome of the pregnancy.

Technical Approach: Forty pregnant women will be selected from both the Family Practice and Obstetrics Clinics. The women will be divided into exercise and control groups of equal size, matched for age, parity, and race.

Progress: Study locally approved in Sep, not yet implemented.

Detail Summary Sheet

Date 20 Oct 83	Prot No., 78-38	Status, Ongoing
Title, Efficacy of Immunotherapy for Systemic Allergic Reaction to Imported Fire Ant Stings. Part I. Human Immunologic Reactivity to Fire Ant Antigens. BB IND 1452		
Start Date,	Est Comp Date,	
Principal Investigator(s) Chester T. Stafford, M.D., COL, MC	Facility, DDEAMC	
Dept/Svc. Medicine/Immunology Clinical Investigation	Associate Investigators. Robert B. Rhoades, M.D., Medical College of Georgia Charles J. Hannan, Jr, PhD, CPT, MSC	
Key Words,		
Accumulative MEDCASE Cost.	Est Accumulative OMA Cost.	Periodic Mar 83 Review Results Continue

Study Objective. 1) To compare the skin test reactivity of fire ant venom and its components with whole body extracts (WBE) of fire ants in patients allergic to stings of the imported fire ant. 2) To compare skin test reactivity with in vitro immunologic studies (RAST and Histamine release). 3) To determine the pretreatment immunologic status of fire ant sensitive patients prior to their participation in studies comparing the relative efficacy of immunotherapy with fire ant venom (Part III protocol) versus whole body extracts (Part II protocol) versus placebo, pending DA approval. Part IV on separate summary sheet).

Progress. Some lots of venom and most lots of WBE have been completely evaluated under Protocol 78-38, Part IV, therefore, the patients now being identified as in need of fire ant immunotherapy will be evaluated and a treatment regimen begun. To this date (3 Oct 83) no patients have as yet been entered in this study.

Detail Summary Sheet

Date 24 Oct 83	Prot No., 78-38	Status, Ongoing
Title, Efficacy of Immunotherapy for Systemic Allergic Reaction to Imported Fire Ant Stings. Part IV - <u>In Vitro</u> Testing of Allergenic Substances. BB IND 1452.		
Start Date, Aug 79	Est Comp Date:	
Principal Investigator(s) Chester T. Stafford, M.D., COL, MC	Facility, DDEAMC	
Dept/Svc, Medicine/Immunology, Clinical Investigation	Associate Investigators, Charles J. Hannan, Jr, PhD, CPT, MSC Robert B. Rhoades, M.D., Medical College of Georgia	
Key Words,		
Accumulative MEDCASE Cost.	Est Accumulative OMA Cost.	Periodic Review Results

Study Objective. Parts I, II and III of this protocol will be conducted under regulations for an Investigational New Drug (IND) and, therefore, production lots of allergens produced at DDEAMC must be subjected to a series of specific evaluations. Tests to be performed include evaluation of: 1) potency, 2) general safety, 3) sterility, and 4) purity as specified in Title 21, Code of Federal Regulations.

Progress. All in house in vitro testing has been completed on two lots of aqueous phase venom and eight lots each of front end and abdominal end ant extract. All lots passed the tests of purity, sterility and general safety. The final category of testing, potency, is partially complete. The phospholipase assay has been completed by the Clinical Investigation Department, however, the RAST, to be completed by arrangement with Dr. Harold Baer, FDA, has not yet been completed on all lots of ant product. Because most lots have been completed, those finished are now available for use in the clinical phase of this protocol.

Detail Summary Sheet

Date: 18 Jul 83 Prot No.: 80-14 (WRAMC 7915) Status: Terminated
 Title: Prevention of Gonadal Damage in Women Treated with Combination Chemo-
 Therapy or Radiotherapy Below the Diaphragm for Hodgkin's or Non-Hodgkin's
 Lymphoma.

Start Date:	Est Comp Date:
Principal Investigator(s)	Facility:
Steven A. Madden, M.D., MAJ, MC	DDEAMC
Dept/Svc:	Associate Investigators:
Medicine/Hematology-Oncology	
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Nov 82 Review Results Terminate
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Study Objective: To determine whether suppression of gonadal function by oral contraceptives in females will protect these individuals from subsequent damage to the gonads and sterility as a result of radiation therapy or chemotherapy for the treatment of Hodgkin's disease or non-Hodgkin's lymphoma.

Technical Approach: Pre-treatment, the patients will undergo an endocrine evaluation including baseline LH, FSH, prolactin and estradiol along with menstrual history. If possible, ovarian biopsy will be obtained pretreatment. The women will be placed on oral contraceptives. The patients will remain on these agents throughout their therapy and at the completion of chemotherapy and/or radiation therapy, their endocrine evaluation will be repeated. Biopsies will not be repeated.

Progress: None. No patients were entered into study.

Detail Summary Sheet

Date: 18 Jul 83		Prot No.: 80-15 (WRAMC 7810)		Status: Terminated	
Title: Prevention of Gonadal Damage in Men Treated With Combination Chemotherapy/Radiotherapy for Hodgkin's Disease and Non-Hodgkin's Lymphomas.					
Addendum #1 to WRAMC Protocol 7810.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Steven A. Madden, M.D., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Medicine/Hematology-Oncology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Nov 82 Review Results Terminate	

Study Objective: To prevent permanent infertility and alterations in normal sexual function caused by combination chemotherapy in the treatment of Hodgkin's disease of histiocytic lymphoma. This is to extend WRAMC Protocol 7810 which was limited to Hodgkin's disease and histiocytic lymphoma.

Technical Approach: To study men ages 18-45 with Hodgkin's disease or non-Hodgkin's lymphoma prior to chemotherapy or infradiaphragmatic irradiation. Patients who have previously received chemotherapy or infradiaphragmatic irradiation will be excluded from this study, as will patients with known history of infertility, chromosomal abnormalities, or prostatic hypertrophy.

Progress: None. No patients were entered into this study.

Detail Summary Sheet

Date: 18 Jul 83 Prot No.: 81-46 Status: Completed
 Title: Programalith-AV

Start Date: May 82	Est Comp Date: May 83
Principal Investigator(s)	Facility:
Kenneth D. Weeks, Jr., M.D., LTC, MC	DDEAMC
Dept/Svc:	Associate Investigators:
Medicine/Cardiology	T. Scott Key, M.D., MAJ, MC
Key Words:	Robert S. Leverton II, M.D., MAJ, MC
	John D. Rathbun, M.D., MAJ, MC
	Joseph J. Cookman, D.O., MAJ, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic May 83 Review Results Completed

Study Objective: To establish the efficacy and safety of dual chamber cardiac pacing (A-V sequential).

Technical Approach: as designated in protocol.

Progress: Since the last periodic review, the pacemaker model under investigation has been approved for commercial use by the FDA. The last implant of this device was made 31 Aug 82 by Dr. T. Scott Key, while still on investigational basis. There were no complications and the pacer continues to serve without dysfunction.

Of the seven patients, there has been excellent follow-up and no important complications, no deaths and no anticipated mechanical failures or manufacturer recalls.

Since the device is now an accepted, approved commercial device, and has proved its functional excellence and durability as well as efficacy, the study can now be terminated.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 81-30 Status: Terminated

Title: In vitro Effect of Cimetidine on Herpes Simplex Virus.

Start Date:	Est Comp Date:
Principal Investigator(s) David A. Jordan, M.D., CPT, MC	Facility: DOEAMC
Dept/Svc: Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To determine if cimetidine possesses anti-viral activity in vitro.

Technical Approach: Using two known strains each of HSV I and II plaque reduction, assays will be performed using various concentrations on cimetidine in the cell culture median. Appropriate controls will also be run. Results will then be determined by the presence or absence of plaque reduction in the tubes containing cimetidine. Some idea of antiviral activity in relation to drug concentration will also be gained.

Progress: None. Project cancelled due to involvement in another project.

Detail Summary Sheet

Date 3 Oct 83 Prot No.: 81-37 Status: Terminated
 Title: Effects of Clostridium difficile Toxin on Ion Transport in Rabbit Ileum and Colon.

Start Date: Sep 81	Est Comp Date:
Principal Investigator(s) William L. Moore, Jr., M.D., COL, MC	Facility: DDEAMC
Dept/Svc: Medicine, Clinical Investigation	Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC Richard W. Harris, CPT, MSC J.P. Rissing, M.D., VAMC T.B. Buxton, ASCP, VAMC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
Study Objective: To examine ion transport in large and small bowel, and changes due to <u>Clostridium difficile</u> toxin.		

Technical Approach: To measure electrolytes in a ligated gut loop and the effect of injection of Clostridium difficile toxin into the solution pumped through the loop.

Progress: Due to the PCS of the principal investigator this protocol has been terminated.

Detail Summary Sheet

Date 18 Oct 83	Prot No.: 81-43 (WRAMC 3168R)	Status: Terminated
Title: Comparison of Modalities for Treatment of SLE Nephritis. Phase I-Split Dose vs Single Daily Dose of SLE Nephritis. Phase II-Chlorambucil Therapy vs Pulse Solumedrol Therapy.		
Start Date: Nov 81	Est Comp Date:	
Principal Investigator(s)	Facility:	
Harold Vonk, M.D., LTC, MC	DDEAMC	
Dept/Svc:	Associate Investigators:	
Medicine/Rheumatology Nephrology	Bruce Edwards, M.D., MAJ, MC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Nov 82 Review Results Continue

Study Objective: 1) To evaluate the efficacy and side effects of single daily dose corticosteroids vs split dose steroid therapy. 2) Provide an alternative form of therapy in patients with SLE Nephritis who have not responded to conventional steroids and to evaluate patients' clinical and serologic response to therapy.

Technical Approach: After completion at prestudy evaluation, patient is randomized to split dose prednisone vs single daily dose prednisone. Weekly kidney function studies and serologic parameters are obtained. After three months, assessment is made if patient is to go to Phase II of the study or if steroid can be reduced. This is an Army-wide cooperative study.

Progress: Total of three patients enrolled in this study in FY 82. The protocol has been found to have inconsistencies which make its practical application difficult. No patients were entered in this study at DDEAMC in the last 12 months. This study can be terminated.

Detail Summary Sheet

Date 18 Oct 83	Prot No.: 81-44	Status: Ongoing
Title: Cardiac Rhythm Disturbances Associated With First Dose Exposure to Doxorubicin.		
Start Date: Oct 81	Est Comp Date:	
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DDEAMC	
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators: Charles Longer, M.D., MAJ, MC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Nov 82 Review Results Continue

Study Objective: To determine whether persons treated with Doxorubicin (Adriamycin) experience cardiac arrhythmias in the 24 hours after initial exposure.

Technical Approach: Holter monitoring performed 24 hours prior and post patient's first exposure to adriamycin.

Progress: Approximately 25 patients at Eisenhower Army Medical Center have been entered into the study, as well as approximately 20 further patients at Brooke Army Medical Center. No incidence of significant arrhythmias after Adriamycin administration have been noted. Protocol will be continued to obtain approximately 50 patients.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 82-1 Status: Terminated
 Title: SWOG 7924, Multimodal Therapy for Limited Small Cell Carcinoma of the Lung, Phase III.

Start Date: Jan 82	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Nov 82 Review Results Continue

Study Objective: 1) To determine the efficacy of sequentially alternating, mutually noncross-resistant, multidrug regimens in remission induction and intensification therapy in patients with limited small cell lung carcinoma. 2) To determine the value of chest radiotherapy added to intensive systemic chemotherapy in reducing chest recurrences, and in improvement of survival. 3) To determine the relative efficacy and toxicity of low-dose, extensive chest radiation when used in close chronologic sequence with systemic multiagent chemotherapeutic regimens. 4) To determine whether radiotherapy ports should be set according to tumor size prior to or after induction chemotherapy. 5) To determine the value of combined systemic chemotherapy and radiotherapy in the control of bulky chest disease.

Technical Approach: Patients with histologically or cytologically proven small cell carcinoma of the lung will be eligible for this study. All patients must have so-called "limited disease."

Progress: No patients were entered into this study. Terminated.

Detail Summary Sheet

Date 18 Oct 83 , Prot No.: 82-2 Status: Terminated
 Title: SWOG 7927/28, Chemotherapy for Multiple Myeloma, Phase III.

Start Date: Jan 82	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Nov 82 Review Results Continue

Study Objective: To compare the effectiveness of four different drug combinations for remission induction in previously untreated patients with multiple myeloma. For patients with a 75% tumor reduction, to evaluate the role of 12 months of chemotherapy maintenance with VSP or VSP plus levamisole, when compared with previous experiences.

Technical Approach: Only previously untreated patients with the diagnosis of multiple myeloma will be eligible for this study. Patients should have objective evidence of and be symptomatic from complications due to myeloma. Therapy will follow schema outlined in the protocol.

Progress: No patients were entered into this study. Terminate.

Detail Summary Sheet

Date 18 Oct 83	Prot No.: 82-3	Status: Ongoing
Title: SWOG 7823/24/25/26 ROAP-AdOAP in Acute Leukemia, Phase III.		

Start Date, Jan 82	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Nov 82 Review Results Continue

Study Objective: 1) To compare the efficacy of the 4-drug combination chemotherapy regimen, ROAP (Rubidazone, vincristine, arabinosyl cytosine, and prednisone) to AdOAP (the same combination using Adriamycin in place of Rubidazone) in adult acute leukemia, as determined by remission rate, remission duration and survival. 2) To determine the comparative toxicity of these regimens. 3) To determine whether late intensification therapy at nine months after complete remission will improve long-term, disease-free survival. 4) To determine whether immunotherapy using levamisole for six months after 12 months of complete remission on chemotherapy improves disease-free survival. 5) To determine the effects of intrathecal Ara-C on the incidence of CNS leukemia. 6) To determine reproducibility of the FAB/histologic classification and correlation to response to therapy in 200 consecutive cases of acute leukemia. 7) To study the effects of intensive supportive care in the management of acute leukemia.

Technical Approach: All patients over 15 with a diagnosis of acute leukemia who have not received extensive therapy (defined as more than one course of any other chemotherapeutic agent or combination of agents) will be eligible for this study. The diagnosis of acute leukemia will be made on bone marrow smear, clot section and/or biopsy. An absolute infiltrate of 50% leukemic cells or greater is required.

Progress: No patients have been entered in this study.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 82-4 Status: Ongoing
 Title: SWOG 8001, Evaluation of Two Maintenance Regimens in the Treatment of Acute Lymphoblastic Leukemia in Adults, Phase III.

Start Date: Jan 82	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Nov 82 Review Results Continue

Study Objective: 1) To evaluate the effectiveness as determined by the complete remission rate of the L10 protocol using Vincristine, Prednisone and Adriamycin for induction, followed by intensive consolidation in the treatment of acute ALL. 2) To compare the effect on remission duration and survival of two maintenance regimens: the L10 "eradication" regimen vs cyclic therapy with POMP-COAP-OPAL. 3) To determine the reproducibility of the FAB histologic classification and correlation to response to therapy of ALL in adults.

Technical Approach: Patients are eligible with the diagnosis of acute lymphoblastic leukemia who satisfy the following criteria: A) Absolute infiltration of the marrow with >50% blasts; absolute infiltration is defined as the total blast cell percentage (%) multiplied by the bone marrow cellularity percentage divided by 100. B) If the absolute infiltrate is 30-49%, evidence of progressive disease prior to entering the study will be required. Therapy will follow the schema outlined in the protocol.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 82-5 Status: Ongoing
 Title: SWOG 7827, Combined Modality Therapy for Breast Cancer, Phase III.

Start Date: Jan 82	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Nov 82 Review Results Continue

Study Objective: 1) To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus chemotherapy and oophorectomy. 2) To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, using one versus two years of combination chemotherapy alone. 3) To compare the disease-free interval and recurrence rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy. 4) To compare the effects of these various adjunctive therapy programs upon the survival patterns of such patients. 5) To correlate the ER status with disease-free interval and survival.

Technical Approach: All patients must have had a radical of modified radical mastectomy with histologically proven breast cancer and with one or more pathologically proven axillary nodes. Primary neoplasm and clinically apparent axillary disease must be completely removed. Pretherapy studies must reveal no evidence of metastatic disease or involvement of the other breast. Patients with postoperative radiation therapy are eligible but will be randomized and evaluated separately. Therapy will follow the schema outlined in the protocol.

Progress: No patients have been entered in this study this year. One patient entered in FY 82 but removed one month later because of intolerance to therapy.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 82-6 Status: Terminated
 Title: SWOG 8012, Treatment for Advanced Adenocarcinoma and Large Cell Carcinoma of the Lung: FOMi vs CAP vs FOMi/CAP, Phase III.

Start Date: Jan 82	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DOEAMC
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Nov 82 Review Results Continue

Study Objective: To evaluate by pairwise comparison the response-rate, duration of response and survival of 3 regimens FOMi, CAP and FOMi/CAP in patients with advanced (TMN Stage III M¹) adenocarcinoma and large cell undifferentiated carcinoma of the lung. 2) To evaluate the degree of non-cross resistance of FOMi in CAP failures and of CAP on FOMi failures. 3) To compare the toxicities and side effects of FOMi and CAP.

Technical Approach: Patients are eligible who have a histologically confirmed diagnosis of adenocarcinoma of the lung or large cell undifferentiated carcinoma of the lung. All patients must have measurable disease. Therapy will follow the schema outlined in the protocol.

Progress: No patients were entered into this study. Terminate.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 82-7 Status: Ongoing
 Title: SWOG 7808, Combined Modality Treatment for Stage III and IV Hodgkin's Disease MOPP #6, Phase III.

Start Date: Jan 82	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc; Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Nov 82 Review Results Continue

Study Objective: To attempt to increase the complete remission rate induced with MOB-BAP alone utilizing involved field radiotherapy in patients with Stages III and IV Hodgkin's disease achieving a partial response at the end of six cycles of MPO-BAP. 2) To determine if immunotherapy maintenance with levamisole or consolidation with low dose involved field radiotherapy will produce significantly longer remission durations over a no further treatment group when complete response has been induced with six cycles of MOP-BAP in Stages III and IV Hodgkin's disease.

Technical Approach: Eligible patients must have a histological diagnosis of Hodgkin's which must be classified by the Lukes and Butler system. Therapy will follow the schema outlined in the protocol.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 82-8 Status: Ongoing
 Title: SWOG 8027, The Natural History of Pathological Stage T₁₋₂N₀M₀ER+ Breast Cancer, Phase III.

Start Date: Jan 82	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Nov 82 Review Results Continue

Study Objective: To document recurrence-rates, patterns of recurrence, and survival among patients with Stage I or Stage II node negative (T₁₋₂N₀M₀) breast cancer whose tumors are determined to be estrogen receptor positive at the time of surgery.

Technical Approach: All female patients having had a radical, modified radical, or adequate local excision, with axillary node dissection for histologically proven breast carcinoma, whose axillary nodes are negative for tumor, and whose estrogen receptor assay on the primary tumor is positive are eligible for this study.

Progress: One patient entered for natural history follow-up.

Detail Summary Sheet

Date 18 Oct 83	Prot No.: 82-9	Status: Ongoing
Title: SWOG 7804, Adjuvant Chemotherapy With 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs Surgery Alone for Patients With Locally Advanced Gastric Adenocarcinoma, Phase III.		
Start Date: Jan 82	Est Comp Date:	
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DDEAMC	
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Nov 82 Review Results Continue

Study Objective: To determine the efficacy of adjuvant chemotherapy with 5-FU, Adriamycin and Mitomycin-C (FAM) on the disease-free interval and survival of patients with TNM stage-groups IB, IC and III gastric adenocarcinoma compared to potentially curative surgery alone.

Technical Approach: Eligible patients must have localized lesions at least extending into the submucosa and involving any of the deeper layers with the maximum allowable penetration into but not through the serosa; localized lesions extending through serosa, with or without direct extension to contiguous structures; a lesion diffusely involving the wall of the stomach with or without metastases to immediately adjacent perigastric nodes or a localized lesion of any depth with metastases to perigastric nodes in the immediate vicinity; a localized or diffuse lesion with metastases to perigastric nodes distant from primary, e.g., greater curvature lesion with metastases to superior gastric nodes. (Group II) on lesser curvature.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 18 Oct 83		Prot No.: 82-10		Status: Ongoing	
Title: SWOG 8006, Preoperative Reductive Chemotherapy for Stage III or IV Operable Epidermoid Carcinoma of the Oral Cavity, Oropharynx, Hypopharynx or Larynx, Phase III.					
Start Date: Jan 82			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC			Facility: DOEAMC		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Nov 82 Review Results Continue	

Study Objective: To determine the length of remission, recurrence-rates, survival-rates, and pattern of recurrence for patients receiving therapy utilizing surgery and postoperative radiation vs combined therapy utilizing preoperative chemotherapy, surgery and postoperative radiation therapy in operable Stage III or IV epidermoid carcinoma of the head and neck.

Technical Approach: Patients with operable lesions will be randomized between two therapeutic programs: Arm I - combined therapy including surgery and postoperative radiation therapy; or Arm 2 - combination chemotherapy followed by surgery and radiation therapy. Patients randomized to the chemotherapy limb will receive three courses of chemotherapy consisting of cis-platinum, methotrexate, vincristine and bleomycin.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 82-11 Status: Terminated
 Title: SWOG 7905, Combined Modality Treatment for ER- Breast Cancer,
 Phase III.

Start Date: Jan 82	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Nov 82 Review Results Continue

Study Objective: 1) To compare disease-free interval and survival among control group Stage I (and Stage II node negative) breast cancer patients whose tumors are determined to be ER- at the time of mastectomy, versus Stage I (and Stage II node negative) ER- patients treated with adjuvant CMFV for 6 months. 2) To document recurrence patterns among untreated patients with Stage I breast cancer whose tumors are determined to be ER- at the time of mastectomy.

Technical Approach: All female patients having had a radical, modified radical or total mastectomy, or segmental mastectomy with axillary node dissection for potentially curable, histologically proven breast carcinoma, whose axillary nodes are negative for tumor, and whose estrogen receptor assay on the primary tumor is less than 10 femtomoles/mg cytosol protein are eligible for this study. Patients must be registered within 28 days of mastectomy. Patients with previous oophorectomy are eligible provided the oophorectomy was not performed for tumor. Therapy will follow the schema outlined in the protocol.

Progress: No patients were entered into this study. Terminate.

Detail Summary Sheet

Date 18 Oct 83		Prot No.: 82-40		Status: Terminated	
Title: SWOG 7902, Combined Modality Therapy With Chemotherapy, Radiotherapy and Surgery vs Radiotherapy and Surgery in Advanced Previously Untreated (Unresectable) Stage III and IV Epidermoid Cancer of the Head and Neck, Phase III.					
Start Date: Jan 82			Est Comp Date:		
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC			Facility: DDEAMC		
Dept/Svc: Medicine/Hematology-Oncology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Nov 82 Review Results Continue	

Study Objective: 1) To compare the survival of Stage II and IV squamous cell carcinoma of the tongue, oral cavity, tonsil, oropharynx, hypopharynx and larynx subjected to radiation therapy followed by surgical excision, if possible, vs survival of patients subjected to chemotherapy with Cis-platinum, Oncovin and Bleomycin (COB), followed by radiation therapy and surgical excision if possible. 2) To determine the incidence and extent of complications arising from chemotherapy and radiotherapy followed by head and neck surgery vs radiotherapy and head and neck surgery.

Technical Approach: Previously untreated patients with a histologically confirmed diagnosis of advanced inoperable squamous cell carcinoma of the head and neck, Stages III and IV, of the oral cavity, tongue, tonsil, oropharynx, hypopharynx and larynx are eligible. There must be an evaluable lesion(s). Patients must have a life expectancy of six weeks or greater. Therapy will follow schema outlined in the protocol.

Progress: No patients entered into this study. Terminate.

Detail Summary Sheet

Date 27 Sep 83 Prot No.: 82-50 Status: Ongoing
 Title: Primary Renal Hematuria: A Prospective Evaluation.

Start Date: Oct 82	Est Comp Date:
Principal Investigator(s) James A. Hasbargen, M.D., MAJ, MC	Facility: DOEAMC
Dept/Svc: Medicine/Nephrology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Review Results

Study Objective: To determine the etiology and significance of hematuria, microscopic and macroscopic, as well as prognosis in patients who have neither personal or family history of renal disease, nor evidence of systemic disease or extrarenal causes of hematuria.

Technical Approach: Patients studied will be over 18 years of age and will have had either gross or microscopic hematuria (the latter defined as greater than ten red blood cells per high-powered microscopic field), intermittently or continuously for at least a three-month period. This will not include urinary tract hemorrhage, i.e., urinary hematocrit of greater than 3% or clot formation. Historical, physical exam and laboratory criteria must be met prior to the patient's entry into the study, and both the patient and the attending physician must be willing to subject the patient to a comprehensive evaluation in accordance with the protocol to include renal arteriography and renal biopsy if indicated.

Progress: Five patients enrolled, with studies completed. No untoward effects or complications.

Detail Summary Sheet

Date 27 Sep 83 Prot No.: 82-51 Status: Ongoing
 Title: IgA Nephropathy: A Prospective Evaluation.

Start Date: Oct 82		Est Comp Date:
Principal Investigator(s) James A. Hasbargen, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Nephrology Pathology		Associate Investigators: Mark Anderson, M.D., MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine pathologic and clinical-pathologic criteria for the diagnosis of IgA nephropathy, the prognosis of patients with such a diagnosis and their suitability for continued military service, the extent of evaluation and degree of followup required for such patients, and the sensitivity and specificity of various noninvasive diagnostic techniques which potentially could obviate the necessity for renal biopsy.

Technical Approach: Patients studied will be over 18 years of age and will have a renal biopsy proven diagnosis of IgA nephropathy. It is realized that such a diagnosis may be made on the basis of the immunofluorescence finding of glomerular IgA deposition, and that there might be differences of opinion between various pathologists concerning diagnostic criteria for this disease entity. Attending physician and the patient must be willing to submit to a comprehensive evaluation to include long-term followup and possibly repeat renal biopsy in accordance with the protocol. Historical, physical exam and laboratory criteria must be met prior to the patient's entry into the study.

Progress: Four patients enrolled, no untoward effects or complications.

Detail Summary Sheet

Date 24 Oct 83 Prot No.: 82-52 Status: Terminated
 Title: Intra-Coronary Streptokinase in Evolving Myocardial Infarction.

Start Date: Oct 82	Est Comp Date:
Principal Investigator(s) Joseph J. Cookman, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Medicine/Cardiology	Associate Investigators: Kenneth D. Weeks, Jr, M.D., LTC, MC T. Scott Key, M.D., MAJ, MC Robert S. Leverton II, M.D., MAJ, MC John D. Rathbun, M.D., MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results
Study Objective: To assess the efficacy and safety of intra-coronary streptokinase infusions in patients with acute myocardial infarction.	

Technical Approach: Study will be an open label trial in 30 patients with acute myocardial infarction. Within ten hours following onset of acute myocardial infarction streptokinase will be infused directly into the obstructed coronary artery through a coronary angiography catheter. A minimum of 15 patients will be enrolled, with the onset of symptoms to start infusion not exceeding ten hours. The effects of the study drug will be assessed by selective coronary angiography, hemodynamic parameters obtained by right and left heart catheterization.

Progress: Fifteen patients were entered in this study. There was one complication of a retroperitoneal hemorrhage following streptokinase infusion. There were no deaths. The study was terminated because the procedure was approved by FDA for general use.

Detail Summary Sheet

Date 30 Sep 83 Prot No.: 82-54 Status: Terminated
 Title: Parenteral BRL 28500 (Ticarcillin/Clavulanic Acid)

Start Date: Apr 83	Est Comp Date:
Principal Investigator(s) D. Baxter Craig, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Sep 83 Review Results Terminate

Study Objective: To evaluate the efficacy and safety of BRL 28500 in the treatment of hospitalized adult patient with systemic or urinary tract infections caused by susceptible aerobic and anaerobic pathogenic bacteria.

Technical Approach: Per Protocol 20311-01, Beecham Labs.

Progress: Unable to obtain suitable candidates. Study terminated.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 83-6 Status: Ongoing
 Title: Treatment of Advanced Testicular Cancer With VP-16 213.

Start Date: Nov 82	Est Comp Date:
Principal Investigator(s) Steven A. Madden, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: 1) To evaluate response rate and survival of patients with advanced, nonseminomatous germ cell neoplasms treated with combination chemotherapy with VP-16 213, vincristine, cyclophosphamide, actinomycin-D, vinblastine, bleomycin and cis-platinum. 2) To determine the toxicity of combination chemotherapy in the following areas: hematologic, gastrointestinal, pulmonary, renal, auditory, dermatologic and neurologic. 3) To develop a psycho-social profile of patients with testicular cancer prior to, during and following treatment in order to derive a more effective overall patient care plan.

Technical Approach: All patients are to be clinically staged according to staging system (Appendix A of protocol). All patients entered on this study will undergo psycho-social evaluation by written testing and by personal interview prior to initiation of each cycle of therapy and after completion of 4 cycles of therapy or at the time of discontinuation of therapy. In addition, those patients who achieve a complete remission will be re-evaluated at 6 months and at one year.

Progress: Three patients entered into study; one death from progressive disease, two have completed chemotherapy protocol without recurrence.

Detail Summary Sheet

Date 28 Sep 83	Prot No.: 83-11	Status: Ongoing
Title: Cross Reactivity of Fall Weed Pollens as Determined by RAST Inhibition Techniques.		
Start Date: Feb 83	Est Comp Date.	
Principal Investigator(s) Chester T. Stafford, M.D., COL, MC Larry Smith, M.D.	Facility: DDEAMC	
Dept/Svc: Medicine/Allergy	Associate Investigators: Charles J. Hannan, Jr, PhD, CPT, MS Ian Stewart, CPT, MS	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: (1) To determine if there is cross reactivity of several fall weed pollens with ragweed pollen. (2) To eliminate costly antigens used for both testing and treating with immunotherapy if significant cross reactivity is proven. (3) To propose that immunotherapy with the most positively reacting antigen will provide a rise in more clinically relevant blocking IgG antibody.

Technical Approach: High titered ragweed IgE serum will be obtained from multiple donors and pooled together after sensitivity has been shown by positive skin test reactions and/or by RAST titers. This pooled serum will then be used in a RAST inhibition test against other fall weed pollens.

Progress: (1) Approximately 7 cc's of high titered ragweed serum was obtained under informed consent from seven donors who demonstrated 4+ ragweed reactivity by skin testing. Blood was collected by venipuncture, allowed to clot, and the serum was separated by centrifugation. Serum specimens were stored at -20°C. The serum from the donors was 4+ ragweed sensitivity by skin testing with both Hollister-Stier and Pharmacia extracts and a 4+ RAST titer was pooled. This pooled serum will be used in a RAST inhibition test against fall weed pollens. (2) A detailed RAST inhibition protocol has been written. The first run of the RAST inhibition test will be performed as soon as laboratory time and space and all reagents are available.

Detail Summary Sheet

Date 28 Sep 83 Prot No.: 83-12 Status: Ongoing
 Title: Role of Calcium Channel Blockers in Reversible Obstructive Airway Disease.

Start Date: Feb 83		Est Comp Date:
Principal Investigator(s) Chester T. Stafford, M.D., COL, MC Larry Smith, M.D. Kenneth D. Weeks, M.D., LTC, MC		Facility: DDEAMC
Dept/Svc: Medicine Allergy Clinic, Pulmonary Lab		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: (1) To determine if calcium channel blockers have any measureable effects on airway resistance. (2) To determine if patients suffering from both myocardial diseases and Reversible Obstructive Airway Disease (ROAD) will have improvement in symptoms of ROAD when treated with calcium channel blockers.

Technical Approach: Pre and post calcium channel blocker treatment pulmonary function tests will be obtained. This will be done in the Pulmonary Function Lab after the patients have been sent to the Allergy Clinic from Cardiology. No blood will be obtained and no other laboratory procedures will be performed. All patients will be over 21 years old and have a cardiac disease which requires a calcium channel blocking agent. Some will also have a diagnosis of ROAD.

Progress: One patient with COPD and angina was prescribed Nifedipine, 10 mg t.i.d. Pre-treatment pulmonary function studies revealed moderate to severe airways obstruction. Results of repeat tests are pending.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 83-13 Status: Terminated
 Title: RS4/SRT Pacemaker Investigation

Start Date:	Est Comp Date:
Principal Investigator(s) John D. Rathbun, M.D., MAJ, MC	Facility: DOEAMC
Dept/Svc: Medicine/Cardiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Review Results

Study Objective: To examine the appropriateness, efficacy, and safety of this physiologic heart pacemaker in the management and treatment of cardiac disorders which have shown to be improved or controlled by long-term pacing therapy.

Technical Approach: Per Cardiac Pacemakers, Inc. Protocol.

Progress: Study was terminated as of 31 Aug 1983. The reason for termination of this study was the availability of dual-chamber (DDD) physiologic pacemakers with active fixation leads which eliminates the possibility of dislodgement of the atrial lead. This pacemaker was designed primarily to alleviate possible atrial dislodgement and provide a physiologic response to exercise. For approximately the same cost or less, active fixation leads can be implanted as well as a pacemaker which behaves in a more physiologic manner. This study was hence discontinued prior to the implantation of any devices in the best interest of patient care and at a cost savings to the U.S. Government.

Detail Summary Sheet

Date 27 Sep 83	Prot No.: 83-14	Status: Ongoing
Title: Urinary Tract Disease in Patients With Hematuria on Chronic Anti-coagulation, A Prospective Analysis.		
Start Date: Feb 83	Est Comp Date:	
Principal Investigator(s) James A. Hasbargen, M.D., MAJ, MC James J. Baunchalk, M.D., CPT, MC	Facility: DDEAMC	
Dept/Svc: Medicine/Nephrology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the incidences of significant renal disease in patients who have hematuria while on chronic anticoagulation.

Technical Approach: Patients will be selected from the anticoagulated population at DDEAMC and be followed weekly with PT's and U/A's.

Progress: No patients enrolled secondary to other time commitments of the PI's. However, it is anticipated that a significant number of patients will soon be enrolled. CPT Baunchalk will become the sole PI due to PCS of MAJ Hasbargen.

Detail Summary Sheet

Date 27 Sep 83 Prot No.: 83-22 Status: Ongoing
 Title: Use of Isotretinoin in Prevention of Basal Cell Carcinoma.

Start Date:	Est Comp Date:
Principal Investigator(s) Marshall A. Guill, M.D., LTC, MC	Facility: DDEAMC
Dept/Svc: Medicine/Dermatology	Associate Investigators: James K. Aton, Jr., M.D., COL, MC John R. Cook, M.D., LTC, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: To evaluate the effectiveness of low dosage levels of isotretinoin in reducing the incidence of basal cell carcinomas in a high risk population. To examine possible side effects associated with long term administration of low doses of isotretinoin.

Technical Approach: Patients with two or more basal cells in the past three years are eligible for inclusion in the study. After a thorough physical exam, participants are randomized to either the treatment group or the placebo group. The medication is provided by the National Cancer Institute and is double-blinded. We hope to enroll about 150 patients over the first 18 months of the study. Participants take the medication for 36 months, continuing to be followed for the following 24 months for a total of 60 months in the study.

Progress: While the study was due to start 1 October 1983, there has been difficulty at participating institutions with hiring a study coordinator. It now appears that the end of October or first part of November is a more realistic date to begin enrolling patients. Progress has been made in finalizing an interagency agreement for transfer of funds for salary of the coordinator and for various supplies to be utilized in the study.

Detail Summary Sheet

Date 27 Sep 83 Prot'No.: 83-25 Status: Ongoing
 Title: Nitroglycerin in the Treatment of Pain Caused by Ureteral Calculi.

Start Date: Jul 83		Est Comp Date:
Principal Investigator(s) James A. Hasbargen, M.D., MAJ, MC CPT Mark Kozakowski, D.O., CPT, MC Gary Wikert, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Nephrology, Urology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the efficacy of nitroglycerin (NTG) in the relief of pain secondary to the passage of ureteral calculi. Additionally, to assess the ability of NTG to facilitate passage of ureteral calculi.

Technical Approach: Administer placebo and NTG to patients with ureteral colic in a randomized, double blind crossover study. Assess pain relief on a 1 - 10 scale and note time of passage of stone.

Progress: Four patients enrolled with no apparent effect of either placebo or NTG. No untoward effects or complications. Tone generator portion of study deleted due to technical problems in obtaining equipment.

Detail Summary Sheet

Date 4 Oct 83	Prot No.: 83-35	Status: Ongoing
Title: Esophageal Reflux in Patients with Mixed Connective Tissue Disease (MCTD).		
Start Date:	Est Comp Date:	
Principal Investigator(s)	Facility:	
Robert H. Peters, MAJ, MC	DDEAMC	
Dept/Svc:	Associate Investigators:	
Medicine/Gastroenterology		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
Study Objective: To quantitate reflux in patients with MCTD.		

Technical Approach: Esophageal motility and 24· pH monitoring at reflux.

Progress: In the process of identifying patients for this study. Equipment has been checked and is ready.

Detail Summary Sheet

Date 27 Sep 83 Prot No.: 82-14 Status: Completed
 Title: Inpatient Nursing Care Satisfaction Survey.

Start Date: Dec 81	Est Comp Date:	
Principal Investigator(s) Allan E. Shapiro, LTC, ANC	Facility: DDEAMC	
Dept/Svc: Nursing Clinical Investigation	Associate Investigators: Richard A. Sherman, PhD, CPT, MSC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine adult inpatient satisfaction with their nursing care at DDEAMC.

Technical Approach: Distribute anonymous response survey to all inpatients on participating wards when they receive their discharge orders. Collect sufficient surveys from each ward so that a sufficient number are collected from each to be representative of its population.

Progress: This project has been brought to a reasonably successful conclusion. Although too few patients on some wards responded to permit definitive interpretation of the results, the overwhelming majority of respondents were highly satisfied with most aspects of their nursing care.

Detail Summary Sheet

Date 5 Apr 83	Prot No.: 82-17	Status: Completed
Title: The Effects of Anesthetic Gases and Vapors on Pulmonary Surfactant Surface Tension.		
Start Date: Dec 81	Est Comp Date: Nov 82	
Principal Investigator(s) Raymond W. Griffith, CPT, ANC	Facility: DDEAMC	
Dept/Svc: Nursing/Anesthesiology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if gases and vapors routinely used in the clinical practice of anesthesia interfere with the surface active capability of pulmonary surfactant.

Technical Approach: Washings from human lungs were obtained at autopsy and the surfactant was purified utilizing the Folch procedure, after lyophilization of the specimen. The surfactant was then floated on saline and a DuNruy surface tension meter was used to measure surface tension during exposure to varying concentrations of oxygen, nitroprusside, and halothane.

Progress: Based on the results of this study, the hypothesis was rejected. There was a significant decrease in the surface tension of pulmonary surfactant exposed to 50% nitrous oxide, and a mixture of 60% nitrous oxide, 40% oxygen, and 2.0, 2.5, and 3.0% halothane. The decrease appeared to be due to the nitrous oxide only and was concentration, as well as time dependent.

Recommendations for further study: This study should be repeated using the following modifications to the experimental protocol: 1) Increase the number of runs for each agent to ten. 2) Increase the time of exposure at each concentration to four minutes. 3) Analyze the surfactant obtained after the purification procedure to determine phospholipid content.

Detail Summary Sheet

Date 27 Sep 83 Prot No.: 82-45 Status: Terminated
 Title: Ambulatory Surgery Research Program.

Start Date: Jul 82	Est Comp Date:
Principal Investigator(s) Bonnie Jennings, MAJ, ANC	Facility: DDEAMC
Dept/Svc: Nursing Clinical Investigation	Associate Investigators: Richard A. Sherman, PhD, CPT, MSC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To gather data on agreeable subjects for the first three years of the program's existence to evaluate program and modify as indicated. To assess efficacy of patient education. To evaluate various educational and surgical modifications (i.e., presurgical relaxation training effects postoperatively).

Technical Approach: Use of questionnaires preoperatively, on day of surgery, and after discharge. Patient education preoperatively via pamphlet, one on one teaching, and postoperatively before discharge. Once a stable population is identified, employ presurgical relaxation tapes.

Progress: A total of 96 subjects were enrolled in the study, and their questionnaires have all been scored. Data need to be analyzed and the study needs to be prepared for submission for publication. The study was terminated on 8 Jul 83 when MAJ Jennings left the Ambulatory Surgery Center (ASC). It was believed that staff personalities and approaches to patients could be significantly different, thereby affecting patient responses. The census in the ASC never allowed for identification of a population with whom to use the relaxation tapes.

Detail Summary Sheet

Date 27 Sep 83 Prot No.: 82-49 Status: Ongoing
 Title: The Use of Social Support by Rheumatoid Arthritic Women from Different Cultural/Ethnic Backgrounds.

Start Date: Sep 82	Est Comp Date:
Principal Investigator(s) Vickie A. Lambert, RN, D.N.Sc. Clinton E. Lambert, Jr., CPT, ANC	Facility: Medical College of Georgia DDEAMC
Dept/Svc: Nursing	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: To identify differences in the nature of the relationships between three types of social support and psychological well-being in rheumatoid arthritic women from three different cultural/ethnic backgrounds.

Technical Approach: Administration of three structured questionnaires by way of interview. Interview to be conducted while subject waiting for scheduled clinic appointment with rheumatologist.

Progress: As of September 1983, 58 of a projected 90 interviews were completed. Data collection is still in progress.

Detail Summary Sheet

Date 18 Oct 83	Prot No.: 83-15	Status: Completed
Title: The Clinical Effectiveness of the BRETHAID Heat and Moisture Exchanger During General Endotracheal Anesthesia.		
Start Date: Feb 83	Est Comp Date:	
Principal Investigator(s) Bernie J. Ferdig, CPT, ANC William C. Higgins, CPT, ANC David G. Brown, CPT, ANC Elbert C. Thornton, 1LT, ANC William C. Floyd, CPT, ANC	Facility: DDEAMC	
Dept/Svc: Nursing/Anesthesiology Course	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if the BRETHAID heat and moisture exchanger can be clinically effective in the conservation of body heat, as reflected by core temperature, during general endotracheal anesthesia.

Technical Approach: Once the patient is anesthetized, the BRETHAID will be placed between the endotracheal tube and the breathing circuit in the experimental group. The core temperature of the experimental and control groups will be monitored and recorded every 15 minutes throughout the surgical procedure using an esophageal temperature probe. Accuracy of these instruments will be tested weekly.

Progress: Total of 36 patients were enrolled in this study. Data collection with statistical analysis has been completed. Presently working on final draft of research paper. There were no significant findings.

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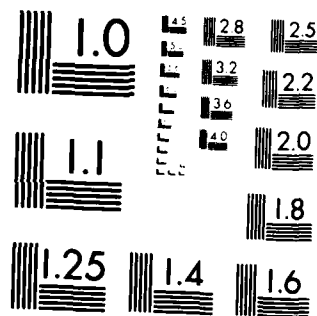
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Detail Summary Sheet

Date 19 Oct 83 Prot No.: 83-16 Status: Completed
 Title: Preparation for Cardiac Catheterization: Sensory Instruction.

Start Date: Feb 83		Est Comp Date: Jun 83
Principal Investigator(s) Vicki R. Odegaard, CPT, ANC		Facility: DDEAMC
Dept/Svc, Nursing/Cardiology		Associate Investigators:
Key Words:		Linda W. Taylor, CPT, ANC Laurence O. Watkins, M.D., MCG
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: The major hypothesis is that slide-audio instructions describing cardiac catheterization, which incorporate information on sensations to be experienced will be more effective in reducing anxiety and psychophysiologic arousal than similar instructions lacking such components.

Technical Approach: Patients were assigned to three groups. One group viewed a slide-audio program designed to provide basic cardiovascular structure and on procedures that occur during catheterization. Second group viewed a program identical to group one with the addition of information on sensations experienced during catheterization. Control group received no intervention and derived whatever information they obtained about cardiac catheterization from attending physicians and other health professionals.

Progress: Data indicate that subjects who receive any type of instruction, either sensory or procedure, before cardiac catheterization report less anxiety in the course of catheterization and are judged by the attending cardiologist to be better adjusted than those who received no instruction. This justifies the use of such audiovisual instruction in patient education. Patient coping style also has significant effects on the levels of anxiety reported during cardiac catheterization. There appears to be significant interaction between coping style and level of information provided in their effects on state anxiety, cooperation during cardiac catheterization and heart rate, an indicator of sympathetic arousal, during catheterization.

Detail Summary Sheet

Date 19 Oct 83	Prot No.: 83-26	Status: Ongoing
Title: Sixteen Personality Factor Profile Responses and Demographic Data Used as Predictors of Final Student Rankings in a Practical Nurse Course.		
Start Date: Jul 83	Est Comp Date: Jun 84	
Principal Investigator(s) Joseph M. Mucha, Jr., CPT(P), ANC	Facility: DDEAMC	
Dept/Svc: Nursing	Associate Investigators:	
Key Words: Predictors of Final Student Rankings		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
Study Objective: To utilize a demographic and personality questionnaire to identify those students who will be successful in completing the Practical Nurse Course.		

Technical Approach: Practical Nurse Course students did a one-time completion of the Sixteen Personality Factor Profile and investigator-prepared Demographic Data questionnaires.

Progress: On 5 July, 31 Practical Nurse Course students were seated in their classroom where the principal investigator verbally explained the objective of the project, grading of it, maintaining students' anonymity, storage of answers, and consent forms. The students were then given a five-minute break to decide whether they wanted to participate or not participate. Approximately 25 students elected to participate. The questionnaire grader was in the back of the classroom as a witness for the consent forms and collected the completed questionnaires. Once graded the questionnaires were taken to Dr. Rath at the Department of Outpatient Psychiatry for storage. No faculty member has seen the results and they will not be looked at until February 1984 when graduation occurs and students' final class rankings are completed.

It is the principal investigator's plan to test the new incoming students in November 1983 and April 1984.

Detail Summary Sheet

Date 30 Sep 83 Prot No.: 83-28 Status: Ongoing
 Title: Family Childrearing Styles, Child Medical Fears and Maternal Presence
 as Predictors of Young Children's Response to Pain.

Start Date: Aug 83		Est Comp Date: May 84
Principal Investigator(s) Marion E. Broome, RN, MN, Doctoral Student Cynthia Moen-Nogueras, MAJ, ANC		Facility: DDEAMC
Dept/Svc: Nursing Pediatrics		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To gather data on the relationship between a parent's presence, his/her childraising practices, the child's sensitivity to medical events and how the child responds to pain produced by an injection.

Technical Approach: Data was collected at five different points during the pre-school screening process. Consent was obtained prior to data collection for each parent/child pair. Data collection involved questionnaires filled out by the parents, interviews with the child and observation of both child and parent behavior during the injection.

Progress: Data is currently being scored and entered into the computer.

Detail Summary Sheet

Date 28 Sep 83		Prot No.: 83-38		Status: Ongoing	
Title: A Measure of Satisfaction in Childbirth: The Degree of Women's Fulfillment of Childbearing Expectations.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Paulette A. Cooke, MAJ, ANC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Nursing					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To operationalize the concept of satisfaction as it pertains to the labor and delivery experience. The goal is to test a tool which purports to measure the degree of satisfaction with the labor and delivery experience.					

Technical Approach:

Progress: Study locally approved in Sep, not yet implemented.

Detail Summary Sheet

Date 3 Oct 83	Prot No., 83-31	Status: Ongoing
Title: Patient Admission Anxiety and Its Effect on Length of Stay.		
Start Date: Sep 83	Est Comp Date: Dec 83	
Principal Investigator(s) James A. Halvorson, CPT, MSC	Facility: DDEAMC	
Dept/Svc: Patient Administration Division	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
Study Objective: To determine a relation, if any, between admission anxiety and length of stay (LOS).		

Technical Approach: Volunteer patients complete the State Trait Anxiety Inventory (STAI). Length of stay is determined upon discharge. Results are compared with the average LOS for that particular diagnosis in DDEAMC during 1982.

Progress: 150 patients have volunteered. More are needed to determine possible correlation. Project will continue through October and November to increase sample size.

Detail Summary Sheet

Date 26 Sep 83 Prot No.: 81-20 Status: Terminated
 Title: Steroid Receptor Status of Cells Grown in Tissue Culture Started From Human Malignant Stem Cells.

Start Date: Apr 81	Est Comp Date: Mar 83
Principal Investigator(s) Cherry L. Gaffney, M.D., CPT, MC	Facility: DOEAMC
Dept/Svc: Pathology Clinical Investigation	Associate Investigators: James C. McPherson III, PhD, DAC Robert W. Prior, MT, DAC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To establish clones from individual malignant stem cells, preferably from breast cancers, and to determine estrogen and progesterone receptor status of numerous clones as well as the individual cells within the clones.

Technical Approach: Harvesting cells from malignant effusions, separating out the tumor cells, and planting the tumor cells in semi-solid cell culture. Estrogen and progesterone receptor status will be determined by a fluorescent stain recently marketed by Zeus which we are investigating in Protocol 81-21.

Progress: No new patients have been presented with malignant effusions to allow refinement of the sample handling techniques necessary for clone growths. However, a number of technical problems have been addressed. These include pH changes occurring in the two different semi-solid cell culture media which has affected clone growths in previous tissue culture experiments and the development of new separation techniques to allow the separation of blood cells from the malignant effusions without additional shock to these cells. This protocol has been terminated due to the principal investigator's transfer.

Detail Summary Sheet

Date 26 Sep 83 Prot No.: 81-21 Status: Terminated
 Title: An Evaluation of the Fluorescent Cytochemical Detection of Steroid Receptor Positive and Negative Cells in Human Breast Carcinoma.

Start Date: May 81	Est Comp Date: Mar 83
Principal Investigator(s) Cherry L. Gaffney, M.D., CPT, MC	Facility: DOEAMC
Dept/Svc: Pathology	Associate Investigators: Janet Riggsbee, MT, DAC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: There is a new method of determining estrogen and progesterone receptor (ER-PR) status of tissue by use of fluorescent cytochemistry. We are using Zeus Chemicals' newly marketed "Fluorocep" stain. Our study is designed to evaluate our correlation between Fluorocep staining results and the conventional cytosol method results. We are also evaluating reproducibility of results.

Technical Approach: All malignant breast tumors biopsied in our hospital are being evaluated by Fluorocep staining for estrogen and progesterone receptors on the diagnostic frozen section and on a portion of the tissue that is sent to Upjohn for cytosol ER-PR determination. Results will be correlated after sufficient specimens have been evaluated. Unstained frozen sections of breast biopsies are being exchanged with a pathologist at University Hospital, Augusta, GA for Fluorocep staining by both of our labs and results are being exchanged. Results will be correlated after sufficient specimens have been evaluated.

Progress: Departmental procedures have been established and are currently in practice in the Anatomic Pathology Section for routine submission of tissue from breast biopsies to the Serology Section for assessment of estrogen receptor presence by fluorescent cytochemical techniques. These results are being correlated with estrogen receptor analysis from conventional cytosol methods. This protocol has been terminated due to the principal investigator's transfer.

Detail Summary Sheet

Date 7 Oct 83		Prot No.: 81-22		Status: Ongoing	
Title: Immunopathological Identification (Classification) of Lymphomas.					
Start Date: Nov 81			Est Comp Date:		
Principal Investigator(s)			Facility:		
Mark C. Anderson, D.O., MAJ, MC			DDEAMC		
Dept/Svc:			Associate Investigators:		
Pathology			Janet Lamke, MT, ASCP, DAC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To develop an aid in the diagnosis and evaluation of human lymphomas for routine use on biopsy specimens.					

Technical Approach: Old cases; using paraffin sections, will be studied first to evaluate the immunofluorescent technique. From all biopsy lymphnode material, a sampling will be snap-frozen and stored at -70°C. Immunofluorescent testing with various antisera will be performed on each biopsy and results recorded by technologist and analyzed by pathologist. Correlation of other histological procedures and data and resulting diagnosis is the responsibility of the pathologist.

Progress: A reliable procedure for identifying intracellular immunoglobulin on paraffin, formalin fixed tissue. This method is being applied to lymphomas examined in this department. New antisera test kits have recently been obtained to evaluate T/B cell profiles in tissue specimens. This new procedure is being investigated for its application in clinical diagnosis.

Detail Summary Sheet

Date 27 Sep 83		Prot No.: 81-32		Status: Ongoing	
Title: A Comparative Study of Immunofluorescence in Fresh Frozen and Paraffin-Embedded Skin Tissue.					
Start Date: Jun 81			Est Comp Date:		
Principal Investigator(s) Janet H. Lanke, MT, DAC			Facility: DDEAMC		
Dept/Svc: Pathology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To confirm the results of previous investigators, to develop a reliable technique for the processing of paraffin-embedded skin tissue, and to investigate the demonstration of complement deposits in paraffin-embedded skin tissue of patients with certain auto-immune skin disorders.

Technical Approach: In patients suspected of having auto-immune disease, biopsies are routinely taken for immunofluorescent studies and H E sections. Some of the remaining paraffin-embedded tissue will be processed according to various methods that we establish and stained by immunofluorescence antisera.

Progress: This protocol requires positive staining cases with both frozen and paraffin tissue submitted. Due to the decreased frequency of the above mentioned samples, this study has not been able to proceed as scheduled. With renewed support by the Dermatology Service, this study will continue to completion.

Detail Summary Sheet

Date 7 Oct 83	Prot No.: 81-33	Status: Terminated
Title: Evaluation of the Roche Laboratory Isomune LD-1 and Isomune CK-MB Test Kits as Compared to the Helena Laboratories CPK, LDH Isoenzyme Techniques in the Diagnosis of Acute Myocardial Infarction.		
Start Date: Jul 81	Est Comp Date: Sep 83	
Principal Investigator(s) Mark C. Anderson, D.O., MAJ, MC	Facility: DOEAMC	
Dept/Svc: Pathology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost,	Est Accumulative OMA Cost,	Periodic Review Results

Study Objective: A comparison of the Helena and Roche methods of isoenzyme analysis to ascertain the following: a) Ability of each test to discriminate between disease and non-disease states; b) time required for diagnostic profile completion for each methodology.

Technical Approach: Perform routine isoenzyme (Helena methodology) analysis on all patients admitted to MICU for chest pain. Select 25 patients having diagnostic criteria for acute myocardial infarction and choose 25 people admitted for chest pain, but lacking EKG changes and having no evidence of enzyme elevations. On these 50 patients perform the Roche CPK-MB and LDH-1 tests on their routine specimens. This population will be used to make the analysis described in the objectives above.

Progress: This study has been terminated.

Detail Summary Sheet

Date 7 Oct 83 Prot No.: 82-33 Status: Terminated
 Title: Training Laboratory for neonatal Procedures.

Start Date:	Est Comp Date:
Principal Investigator(s) John B. Woodall, M.D., COL, MC	Facility: DDEAMC
Dept/Svc: Pediatrics Clinical Investigation	Associate Investigators: Steven Larson, M.D., LTC, MC J. Bruce Arensman, DVM, MAJ, VC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To familiarize residents on rotation through the Department of Pediatrics with some emergency procedures in the newborn. Initially, these will be: a) endotracheal intubation; b) thoracentesis for pneumothorax and placement of chest tube; c) umbilical vein and artery catheterization.

Technical Approach: One-half day each month will be scheduled for the residents on rotation in the Department of Pediatrics to receive the proposed training.

Progress: The principal investigator has PCS'd and upon discussion with involved individuals, the objectives of this protocol will be incorporated into a new training protocol currently being developed.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 81-34 Status: Completed

Title: Dexamethasone Suppression Test (DST) in Depression: Clinical and Psychological Correlates and Response to Tricyclic Antidepressants (TCA).

Start Date: Jul 81	Est Comp Date:
Principal Investigator(s)	Facility:
Andrea C. Bradford, M.D., CPT, MC	DDEAMC
Dept/Svc:	Associate Investigators:
Psychiatry and Neurology	
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: 1) Test efficacy of DST in diagnosing major depression; 2) determine whether there are a subset of patients with cortisol hypersecretion and normal DST; 3) determine whether or not there are correlates in family history, psychological test results or response to desipramine or amitriptyline to hypersecretion of cortisol, response to DST or timing of escape from cortisol suppression; 4) determine whether or not cortisol hypersecretion and abnormal DST correct on recovery.

Technical Approach: 1) Baseline 24-hour urine for free cortisol, 0800 and 2300 serum cortisol, psychological testing, depression scales, family history; 2) 1 mg dexamethasone at 2300 followed by 0800, 1600, and 2300 serum cortisol; 3) treatment with tricyclic desipramine or amitriptyline (double-blind) daily depression checklist, weekly depression scales; 4) after four weeks, or upon clinical remission of depression, repeat baseline studies.

Progress: Six patients entered in FY 82, none in FY 83. Sample collection has been completed. Statistical analysis of data is presently underway for research paper.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 82-55 Status: Ongoing
 Title: Relative Accuracy of Adolescent- and Adult-Normed MMPI Profiles in Young Enlisted Military Personnel.

Start Date: Oct 82	Est Comp Date:
Principal Investigator(s) Jerry R. DeVore, PhD, CPT, MSC	Facility: DDEAMC
Dept/Svc: Psychiatry and Neurology/Psychology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To investigate the relative accuracy of behavioral narratives generated by adolescent- and adult-normed profiles.

Technical Approach: Three hypotheses will be tested in this study: 1) behavioral narratives based on adolescent MMPI norms will be rated as reasonably accurate by a group of interviewers familiar with the behavior of the subjects under investigation (i.e., active duty enlisted personnel between the ages of 18 and 21); 2) behavioral narratives based on adolescent MMPI norms will be judged as more accurate than narratives generated by K-corrected or non-K-corrected adult norms; 3) various patient characteristics (e.g., race, sex, education) will not have a major impact on the results.

Progress: At the present time, I am awaiting computer availability in order to process the collected data.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: May 78		Est Comp Date:
Principal Investigator(s) Kenneth Y. Gleitsmann, M.D., CPT, MC John E. Riffle, M.D., COL, MC Tatjana Pavlovic, M.D., CPT, MC John Pope, Jr., M.D., LTC, MC		Facility: DDEAMC
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words: Intraocular Lens Implant Ophthalmology Aphakia Surgery		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 83 Review Results Continue

Study Objective: Implantation of intraocular lenses in accordance with previously established FDA protocol.

Technical Approach: Currently accepted surgical techniques for cataract extraction and intraocular lens implantation using the operating microscope.

Progress: 174 patients through FY 82. 326 patients through FY 83. There have been no complications.

Detail Summary Sheet

Date 18 Oct 83	Prot No.: 82-13	Status: Ongoing
Title: The Efficacy of Single Dose of Metronidazole, Cefoxitin, or Placebo in Preventing Wound Infections Following Appendectomy.		
Start Date: Jan 82	Est Comp Date:	
Principal Investigator(s) James A. Classen, M.D., CPT, MC Ross S. Davies, M.D., COL, MC	Facility: DDEAMC	
Dept/Svc: Surgery/General Surgery	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Jan 83 Review Results Continue
Study Objective: Determine efficacy of single dose antibiotic in emergency appendectomy.		

Technical Approach: Prospective, randomized, double-blind study.

Progress: FY 82 - 17 patients; FY 83 - 50 patients. There have been no complications. The study will continue until 100 patients have been entered.

Detail Summary Sheet

Date 27 Sep 83 Prot No.: 82-46 Status: Completed
 Title: Selective Monocular Deprivation: An Electrophysiological Study.

Start Date: Jul 82		Est Comp Date:
Principal Investigator(s) Jeff Rabin, CPT, MSC		Facility: DDEAMC
Dept/Svc: Surgery/Optomtry		Associate Investigators:
Key Words: Amblyopia, Astigmatism, Monocular deprivation, Neural plasticity		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: If a significant interocular difference in refractive error is not corrected early in life, then the visual acuity of the more defocused eye is often reduced. This condition, known as amblyopia, may reflect a neural anomaly within the visual cortex. However, direct evidence from humans is lacking. The purpose of this study was to investigate the neural basis of amblyopia.

Technical Approach: Visual-evoked cortical potentials (VECPs) were recorded from two groups of anisometropic amblyopes. Group one (N=7) was tested with a pattern-reversal, checkerboard stimulus. Monocular and binocular amplitudes were recorded for a number of check sizes, and compared to values from normal subjects. Group two (N=5) consisted of subjects with high astigmatism limited to the amblyopic eye. The pattern-reversal stimulus was a square-wave grating (horizontal or vertical). Monocular and binocular amplitudes were compared within subjects, across orientation.

Progress: Control measurements from normal subjects confirmed previous findings by demonstrating that VECP amplitude is sensitive to defocus, larger with binocular viewing, and equal for horizontal and vertical orientations. Despite best optical correction, VECP amplitudes from amblyopic eyes were significantly reduced when compared to amplitudes from nonamblyopic (dominant) eyes, and from normals. In some subjects amplitudes were reduced for all check sizes. In contrast to the binocular summation in normal subjects, the VECP from the dominant eye was often larger than the binocular response in amblyopic subjects. This exemplifies the concept that amblyopia is not merely a monocular deficit in acuity, but an anomaly of binocular vision.

In subjects with monocular astigmatism, monocular and binocular VECP amplitudes varied with orientation. Although the type of orientation bias varied

between subjects, this finding suggests that early astigmatism in one eye may alter the orientation preference of the astigmatic, the nonastigmatic eye, and that of both eyes. This points to an influence at a binocular, orientation selective level; presumably within the visual cortex. Additional electrophysiological study of monocular astigmatism with rigorous psychophysical measurements will contribute to our understanding of the neural basis of amblyopia.

Publications

Rabin J: The visual-evoked response in anisometropic amblyopia. In Press, 1984, Optometric Monthly.

Rabin J: Monocular astigmatism: Preliminary findings with visual-evoked cortical potentials. Submitted to Am J Optometry Physiological Optics.

Detail Summary Sheet

Date 19 Oct 83		Prot No.: 82-57		Status: Ongoing	
Title: Utilization of the Bascom Technique in the Treatment of Acute and Chronic Pilonidal Abscess Disease.					
Start Date: Oct 82			Est Comp Date:		
Principal Investigator(s)			Facility:		
Kerrey B. Buser, M.D., CPT, MC			DDEAMC		
Guillermo Quispe, M.D., MAJ, MC			Associate Investigators:		
Dept/Svc:					
Surgery/General Surgery					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To ascertain if the application of the Bascom technique will decrease disability and/or hasten healing time in acute pilonidal disease.

Technical Approach: All acute and chronic pilonidal abscesses seen by the Surgical Service at DDEAMC are to be treated according to the techniques described by Dr. Bascom. The patients will be treated as outpatients. During duty hours, Dr. Buser and/or Dr. Quispe will see all patients included in this study and will provide treatment. The patients will be seen at least once a week until total healing has taken place. At the completion of the study, disability time and healing time will be assessed and a comparison will be made with Dr. Bascom's results.

Progress: Four patients entered into study. The results show good healing of wounds by two weeks post treatment and total healing averaging three weeks. There have been no reports from the patients' companies indicating they could not perform assigned duty the day following the operation (a major goal of the protocol). We plan on continuing the study until we acquire approximately 50 patients, at which time we will re-evaluate our results and perhaps submit them to a major surgical journal for potential publication.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 83-5 Status: Ongoing
 Title: XM-72 Nonabsorbable Monofilament Suture.

Start Date: Jun 83	Est Comp Date:
Principal Investigator(s) Roberto H. Barja, M.D., COL, MC	Facility: DDEAMC
Dept/Svc: Surgery/Orthopedic	Associate Investigators: Orthopedic Staff Physicians
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To compare XM-72 and Prolene sutures in terms of tissue reaction, efficacy and handling properties including suppleness, tissue drag and knotting properties, i.e., rundown and knot security.

Technical Approach: Fifty patients will be entered into the study at random. These will be both male and female requiring various surgical procedures. Half of the patients will be sutured with experimental suture and half with Prolene. Terminally ill patients will be excluded.

Progress: To date 15 patients have been enrolled in this double blind study. There have been no complications.

Detail Summary Sheet

Date 4 Oct 83	Prot No.: 83-17	Status: Ongoing
Title: Comparison of Efficacy of Metronidazole in an Animal Model.		
Start Date: Feb 83	Est Comp Date:	
Principal Investigator(s) William M. Steely, M.D., CPT, MC	Facility: DDEAMC	
Dept/Svc: Surgery Clinical Investigation	Associate Investigators: Ross S. Davies, M.D., COL, MC Richard W. Harris, CPT, MSC J. Bruce Arensman, DVM, MAJ, VC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To examine the effects of antibiotics on monomicrobial and polymicrobial abscesses in a rabbit model.

Technical Approach: Sterile plastic perforated capsules were implanted i.p. into New Zealand white rabbits and held 6 weeks to become encased in a layer of connective tissue. An attempt was then made to treat the animals with metronidazole to determine penetration of the antibiotic in sterile capsule capsule.

Progress: The low pH (1.0) of metronidazole prevented i.m. injection. The jugular vein of the rabbits was then catheterized with a permanent indwelling catheter. An investigation is now underway to determine if a slow infusion of metronidazole at higher pH will produce adequate serum and capsule concentrations during a seven day therapy.

Detail Summary Sheet

Date 19 Oct 83 Prot No.: 83-23 Status: Ongoing
 Title: Solute Diuretic Effect of Endogenous Urea in Gastrointestinal Bleeder.

Start Date:	Est Comp Date:
Principal Investigator(s) Kerrey B. Buser, M.D., CPT, MC	Facility: DDEAMC
Dept/Svc: Surgery Clinical Investigation	Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC James C. McPherson, III, PhD, DAC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To determine the amount and the significance of water loss due to the urea solute diuresis in dogs.

Progress: Not yet implemented.

Detail Summary Sheet

Date 19 Oct 83 Prot No.: 83-24 Status: Ongoing
 Title: Assessment of Vertical Banded Gastroplasty in Treatment of Morbid Obesity.

Start Date: Apr 83	Est Comp Date:
Principal Investigator(s) Ross S. Davies, M.D., COL, MC Robert Chadband, M.D., MAJ, MC David T. Armitage, M.D., COL, MC	Facility: DOEAMC
Dept/Svc: Surgery Medicine Psychiatry and Neurology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: To determine if vertical banded stapling is an effective treatment modality for morbid obesity, to determine its long term effectiveness and complications, and to determine if it will prevent the detrimental effects of morbid obesity.

Technical Approach: Weight loss post bypass will be studied in each patient and compared to average weight loss from other centers following the same procedure. Psychologic testing post-operative will be compared to pre-operative results to examine patient self-image pre and post weight loss.

Progress: Twelve patients have undergone vertical banded gastroplasty since initiation of this protocol. There have been no operative deaths and no significant complications except for one patient who had an iatrogenic splenectomy. All patients have experienced weight loss; however, it is too early to make a final determination of the ultimate success of the project. An additional 20 patients have been evaluated and are in various stages of preoperative work-up.

Detail Summary Sheet

Date 7 Oct 83		Prot No.: 83-30		Status: Ongoing	
Title: Use of Spring Loaded Silastic Discs as a Prosthesis for Cervical Intervertebral Discs.					
Start Date, Jun 83			Est Comp Date:		
Principal Investigator(s) Nabil L. Muhanna, MAJ, MC			Facility: DDEAMC		
Dept/Svc: Surgery/Neurosurgery Clinical Investigation			Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To study the suitability of spring loaded silastic discs as a prosthesis for cervical intervertebral discs in the normal canine.

Technical Approach: Using a vertebral approach the vertebral bodies of C₂ through C₆ are exposed. Three intervertebral spaces are identified, the disc material is removed and a silastic prosthesis is inserted. Sutures are placed to secure the prosthesis, and the surgical site is closed. Healing and placement of the prosthesis is monitored by radiographic examination, and routine physical examinations. At approximately four months the animals will be sacrificed and the vertebral sites examined both grossly and histologically.

Progress: Four dogs have been operated to date, and one pending necropsy at the appropriate interval.

Detail Summary Sheet

Date 18 Oct 83		Prot No., 83-33		Status, Ongoing	
Title, Reflux Esophagitis in Morbid Obesity and the Effects of Vertical Banded Gastroplasty.					
Start Date,			Est Comp Date:		
Principal Investigator(s)			Facility,		
Frank G. Opelka, CPT, MC			DDEAMC		
Ross S. Davies, COL, MC			Associate Investigators:		
Dept/Svc.					
Surgery					
Key Words,					
Accumulative MEDCASE Cost.		Est Accumulative OMA Cost.		Periodic Review Results	

Study Objective. To evaluate the potential for reflux esophagitis in the morbidly obese patient, before and after vertical banded gastroplasty.

Technical Approach. In addition to a preoperative history and physical, each patient will be evaluated and scored for symptoms of gastroesophageal reflux according to the method of Iascone et al.

Progress. Four patients have been entered into the study, however, not all details of the protocol are complete. Specifically, the agreement between General Surgery and GI concerning the details of postop endoscopy and its frequency. This should be completed by mid-November.

Detail Summary Sheet

Date 19 Oct 83	Prot No.: 83-21	Status: Ongoing
Title: Married Couples Group Therapy: A Clinical Investigation		
Start Date: Nov 83	Est Comp Date:	
Principal Investigator(s) James L. Maury, MAJ, DSW, MSC Shirley M. Walley, Graduate Student	Facility: DDEAMC	
Dept/Svc: Social Work Service Family Practice	Associate Investigators: Ronald J. Platte, LTC, PhD, MSC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
Study Objective: To measure the effect of a married couples group therapy on marital interaction.		

Technical Approach: Five married couples referred by their family physician for marital therapy will initially be seen alone as a couple in order to: obtain their consent to participate; establish a therapeutic relationship; identify basic demographic data; and administer the marital adjustment scale. All five couples will then be seen together in group therapy for 1½ hours once per week for eight weeks. At the end of eight weeks, each couple will be interviewed alone and readministered the marital adjustment scale. The data will be analyzed using standard social science research statistics.

Progress: Project not yet implemented due to temporary loss of support personnel. Plan to start in Nov 83.

Detail Summary Sheet

Date 13 Oct 83 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: Nov 80	Est Comp Date:
Principal Investigator(s) Thomas W. Grabow, M.D., LTC, MC John M. Hope, M.D., MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Surgery/Ophthalmology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 83 Review Results Continue
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Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical insertion of intraocular lens. Presently, the lenses used have been a Tennant/Anchor Anterior Chamber Lens, a Tennant Anchorflex II Lens, a Pannu Anterior/Posterior Chamber Lens, an IOLAB J-Loop Lens, the McGhan 34S Modified Sheets Lens and a Liteflex Lens.

Progress: Prior number of subjects: 143.

During this FY we have implanted an additional 60 intraocular lenses; 45 of them have been anterior chamber lenses; the bulk have been Tennant/Anchor Anterior Chamber Lenses, although Pannu Lenses have been implanted in the anterior chamber in five individuals. During this past year, we have also transitioned from intracapsular cataract extraction in anterior chamber implantations to extracapsular cataract extraction with posterior chamber implantations. As of 30 September, we have implanted 15 lenses in the posterior chamber.

Detail Summary Sheet

Date 13 Oct 83 Prot No.: 79-25 Status: Ongoing
 Title: The Effect of Guaifenesin in the Treatment of Middle Ear Effusion: A Double Blind Study.

Start Date: Nov 80	Est Comp Date:
Principal Investigator(s) Gregory H. Blake, M.D., MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice	Associate Investigators: Dale A. Carroll, M.D., MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Review Results

Study Objective: To determine whether guaifenesin, a mucolytic agent has a place in the management of middle ear effusion.

Technical Approach: The study is a double blind protocol looking at children aged 2-16 years who have middle ear effusion. Middle ear effusion is diagnosed by clinical history, otoscopic exam, and audiology evaluation. Audiologic criteria are a Type B tympanogram or two of the following: a difference between air and bone conduction hearing threshold level of .15 dB or more on three test frequencies; a maximum compliance change peak which is negatively displaced 100 mm or more from ambient air; and a static middle ear compliance less than 0.26 ml. Half of those patients agreeing to enter the study will be given guaifenesin and the other half the base of guaifenesin. Patients will be followed for clinical and audiologic improvement at two and four weeks.

Progress: 12 subjects thru FY 82. Study still with 12 subjects. Initial data review reveals promising trend but not enough to be diagnostic. Project to be resumed with Dr. Carroll added as co-investigator in the Fall 1983.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 81-12 Status: Terminated
 Title: Comparison of Single-Dose Metronidazole versus Seven Day Metronidazole
 in Patients with Hemophilus vaginalis Vaginitis.

Start Date: Jan 82	Est Comp Date: Oct 82
Principal Investigator(s) John L. Larson, M.D., MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice	Associate Investigators: Gregory H. Blake, M.D., MAJ, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: To determine the efficacy of single dose metronidazole in the treatment of H. vaginalis vaginitis.

Technical Approach: Double-blind clinical trial looking at 100 women age 18-44. Women that are pregnant, have diabetes or blood dyscrasia or other than non-specific vaginal infections will be excluded. A questionnaire will be filled out and exam performed. Patients will be randomly assigned to treatment or placebo group. Followup at 7 and 28 days.

Progress: Principal investigator PCS'd, terminate study.

Detail Summary Sheet

Date 18 Oct 83	Prot No.: 82-23	Status: Terminated
Title: Effect of Hydration, Urine Acidification and Pyridium (HAP) on Bacterial Count in Lower Urinary Tract Bacterial Infections (LUTBI).		
Start Date: Jan 82	Est Comp Date: Oct 82	
Principal Investigator(s) Magdi B. Hanna, M.D., CPT, MC	Facility: USA MEDDAC, Ft Benning, GA	
Dept/Svc: Family Practice	Associate Investigators:	
Key Words: LUTBI-Lower Urinary Tract Bacterial Infection HAP- Hydration, Acidification Pyridium		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: This study was undertaken with the objective of proving the efficacy of a regimen to treat LUTBI that did not require the use of anti-biotics.

Technical Approach: Female patients age 18-40 presenting to the Family Practice Clinic at Martin Army Community Hospital with symptoms of internal dysuria with urinary frequency <72 hours, and who did not meet any of the exclusion criteria; were assigned through a double blind approach to one of two groups of treatment. The first group received Amoxicillin 500 mg, 6 tabs one dose + pyridium 100 mg, 2 tabs tid x 5 dosages + placebo divided p.o. qid x 7d. The second group received 6 placebo tabs one dose initially + pyridium as with the first group + vitamin C 500 mg p.o. qid x 7d + instructions to increase water intake to 12 fl oz 8 x 1d. Diagnostic criteria for inclusion required unspun urine of patient with ≥ 2 bacteria/OIF and ≥ 2 WBC/HPF. Urines were cultured and U/A repeated on days 1,3,5,7,10 and 28.

Progress: Total of five patients enrolled. Terminated at request of principal investigator. Not enough data for project to be evaluated.

Detail Summary Sheet

Date 13 Oct 83 Prot No.: 82-24 Status: Completed
 Title: The Efficacy of Education on Training Time Lost Due to Tobacco
 Related Illnesses.

Start Date: Jan 82	Est Comp Date:
Principal Investigator(s) Gregory H. Blake, M.D., MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice	Associate Investigators: Wayne G. Stanley, M.D., CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To determine whether an educational process, in this case a slide series, can modify behavior related to tobacco use. Also to determine whether tobacco use adversely affects the amount of time a soldier in BCT is involved in training.

Technical Approach: A questionnaire was given to six companies (240 men ea) to determine smoking habits. Two companies were evaluated each week. One received a talk on tobacco use and the other acted as a control. All TMC visits and hospitalizations were evaluated and recorded if discharged from the facility as a URI, bronchitis, sinusitis or pneumonic. All profiles were recorded. Data was evaluated according to whether soldiers were smokers and whether they received the talk. A repeat questionnaire was given to those completing BCT to determine changes in smoking habits.

Progress: Study completed with results presented to Uniformed Services Academy of Family Physicians meeting in Seattle, WA in May 1982 and revised results presented to UMC symposium in June 1983. When status of those trainees not completing BCT in first outing is determined then papers will be submitted for publication.

Detail Summary Sheet

Date 13 Oct 83 Prot No.: 82-36 Status: Terminated
 Title: Efficacy of a Clinically Directed Lecture Series in Changing Patterns of Caring for Hypertensive Patients.

Start Date: Mar 82	Est Comp Date:
Principal Investigator(s) Larry S. Fields, M.D., MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To assess performance of management of hypertension after an in-depth course.

Technical Approach: Chart audit of before and after the course clinic visits for hypertension using specified criteria.

Progress: Administratively terminated. Principal investigator PCS'd without submitting a final report.

Detail Summary Sheet

Date 13 Oct 83 Prot No.: 82-37 Status: Terminated
 Title: Comparison of Two Modes of Therapy in Acute, Uncomplicated Bronchitis.

Start Date: Mar 82	Est Comp Date:
Principal Investigator(s) Edward M. Friedler, M.D., CPT, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice	Associate Investigators: Danny P. Kaup, M.D., MAJ, MC
Key Words:	John C. Lincoln, III, M.D., CPT, MC

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: To determine efficacy of antibiotics in effecting hospitalization in soldiers with bronchitis.

Technical Approach: Randomized double-blind placebo/antibiotic prospective clinical trial.

Progress: Administratively terminated. Principal investigator PCS'd without submitting a report.

Detail Summary Sheet

Date 20 Oct 83	Prot No.: 82-38	Status: Terminated
Title: Protocol for the Double-Blind Comparison of Ketoconazole (R 41,400) and Griseofulvin in the Treatment of Dermatophyte Infections.		
Start Date:	Est Comp Date:	
Principal Investigator(s)	Facility: USA MEDDAC	
Stephen W. Eubanks, M.D., MAJ, MC	Ft Benning, GA	
Dept/Svc:	Associate Investigators:	
Medicine		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
Study Objective: To employ ketoconazole or griseofulvin on a random basis in the treatment of cutaneous infection due to dermatophytes. The evaluation will be based upon clinical and mycological efficacy and side effects.		

Technical Approach:

Progress: Study was not implemented due to lack of necessary cooperation from drug company. Terminate

Detail Summary Sheet

Date 13 Oct 83		Prot No.: 82-41		Status: Ongoing	
Title: Correction of Myopia Using the Fading Technique.					
Start Date: May 82			Est Comp Date:		
Principal Investigator(s)			Facility:		
Glenn C. Griffiths, M.D., CPT, MC			USA MEDDAC, Ft Benning, GA		
Dept/Svc:			Associate Investigators:		
Family Practice			Thomas W. Grabow, M.D., LTC, MC		
Surgery/Ophthalmology, Optometry			William T. Nimmons, O.D., CPT, MSC		
Key Words,					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To determine if training the eye to focus at progressively greater distances results in improvement in myopia.					

Technical Approach:

1. Test visual parameters of subjects.
2. Subjects begin fading technique using lens system.
3. Vision testing 3 days per week.
4. Retest visual parameters of subjects at 6 and 12 months after training completed.

Progress: Project temporarily on hold as materials were received too late in the year to begin.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 83-1 Status: Ongoing
 Title: Application of Screening Procedure to Determine the Etiology of Microcytosis With or Without Anemia.

Start Date: Oct 82	Est Comp Date:
Principal Investigator(s) Ronald G. Albright, Jr., M.D., MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To evaluate the ability of simple calculations made from information found on the routine Coulter CBC slip to predict the etiology of microcytosis with or without anemia.

Technical Approach: Chart review.

Progress: Chart review in progress; data collection and evaluation ongoing.

Detail Summary Sheet

Date 13 Oct 83 Prot No., 83-2 Status, Ongoing
 Title: Remarried Families: Adaptability and Cohesion.

Start Date: Nov 82	Est Comp Date:
Principal Investigator(s) Perry L. Wolf, III, CPT, MSC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Social Work Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative DMA Cost:
	Periodic Review Results

Study Objective: To study the relationship between family structure and family adaptability and cohesion. The relationship of the intervening variables -- discipline, mythology, and loss -- with adaptability and cohesion will be studied. Role theory and family systems theory will provide a theoretical framework.

Technical Approach: This study will investigate the psychological meaning of adolescent attributes to his/her biological parent and step-parent by comparing the adolescent's appraisal of them along the lines of evaluation, activity, and potency. Each family structure will include a biological mother, her biological child and either a biological father or a step-father. The major independent variable in this study will be defined as family membership in REM family or a biological parent family. Four instruments will be used to collect data on the other study variables.

Progress: Remarried Family Discipline, Myth and Loss (DML) scale has been developed. Instrument was pre-tested and final tested by 80 mental health professionals who work with remarried families. Data gathering is scheduled to begin in January 1984.

Detail Summary Sheet

Date 13 Oct 83		Prot No.: 83-3		Status: Ongoing	
Title: Otitis Media With Effusions: The Efficacy of Vibramycin and a Non-tapering Short Course Prednisone in Adults.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Gregory H. Blake, M.D., MAJ, MC			USA MEDDAC, Ft Benning, GA		
Dept/Svc:			Associate Investigators:		
Family Practice			Frank S. Celestino, M.D., CPT, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To determine the efficacy of steroids in the treatment of otitis media with effusion in adults.					

Technical Approach: Double-blind controlled crossover clinical trial in which 30 active duty soldiers with otitis media with effusion will be studied. Subjects meeting inclusion criteria will be randomly placed in the treatment group or control group by the pharmacist.

Progress: Study to formally begin this fall.

Detail Summary Sheet

Date 13 Oct 83		Prot No.: 83-9		Status: Terminated	
Title: The Time and pH Dependence of the Anion Gap (AG) in Acute Respiratory Acid-Base Disturbances.					
Start Date: Nov 82			Est Comp Date:		
Principal Investigator(s)			Facility:		
William D. Paulson, M.D., MAJ, MC			USA MEDDAC, Ft Benning, GA		
Dept/Svc:			Associate Investigators:		
Medicine/Pathology, Veterinary Activity			William R. Rahm, CPT, MSC		
Key Words:			Robert Southall, DVM, CPT, VC		
			Sam Cucinell, M.D., COL, MC, C, DCI, TAMC		
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: Study will test the hypothesis that the AG is dependent upon both the duration and severity of the change in pH. The concentrations of many of the "unmeasured" ions will be determined in order to characterize the electrolyte changes that occur. Propose to measure the AG during acute hypercapnia and hypocapnia in the dog.

Technical Approach: Fifteen heartworm negative dogs, each with normal serum chemistries, CBC, and serum protein electrophoresis, will be studied for 90 minutes under five different conditions, on different days.

Progress: Terminated. The accuracy and precision of the clinical lab was found to be inadequate for this study.

Detail Summary Sheet

Date 13 Oct 83	Prot No.: 83-10	Status: Ongoing
Title: The Anion Gap in Normal Human Pregnancy.		
Start Date: Nov 82	Est Comp Date: Jun 84	
Principal Investigator(s) William D. Paulson, M.D., MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA	
Dept/Svc: Medicine, OB-GYN, Pathology	Associate Investigators: John Sautlz, M.D., MAJ, MC Glenn Griffiths, CPT, MC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the normal reference value for the anion gap in human pregnancy.

Technical Approach: Seventy-five patients will be enrolled in the study prior to their Obstetrics Clinic visit at 34 weeks. Venous serum will be obtained at the time of entry to the study, then at 34 weeks into the pregnancy, and three months postpartum. Analysis of variance will be used for repeated measures in the same subject to detect differences in the two data groups.

Progress: Data was collected on 23 pregnant volunteers and 7 control volunteers, finding a systematic bias for a low anion gap by the clinical lab. All of this data has, therefore, been discarded.

Data was collected on 21 new pregnant volunteers and 8 control volunteers. The sodium, potassium and chloride are being determined manually with a flame photometer and a chlorideometer. The previously mentioned bias has been eliminated with this procedure and the study is progressing nicely.

Detail Summary Sheet

Date 13 Oct 83 Prot No.: 83-19 Status: Completed
 Title: Content of Family Practice in Non-residency Based Military Settings.

Start Date: Feb 83	Est Comp Date:	
Principal Investigator(s) Gregory H. Blake, M.D., MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA	
Dept/Svc: Family Practice	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Family physicians serve in the United States Army in field units and residence based programs. This study will show how a family physician's practice in a non-residency setting compare with national trends.

Technical Approach: All patients seen in the Family Practice Clinics at Ft Hood and the 197th Inf Bde, Ft Benning will have the Family Practice Center Encounter Form placed in the medical records. The medical receptionist will fill in the demographic information and the health care provider will record the medical information upon completion of the patient encounter. The forms will be collected and analyzed in batch mode at Ft Benning using the Student T-Test.

Progress: Completed. Currently undergoing data evaluation.

Detail Summary Sheet

Date 13 Oct 83 Prot No.: 83-20 Status: Completed
 Title: Antipyretic Effects of Naproxen Sodium.

Start Date:	Est Comp Date:
Principal Investigator(s) Steve E. Phurrough, M.D., MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice	Associate Investigators: Wayne G. Stanley, M.D., CPT, MC John W. Saultz, M.D., CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To evaluate the symptomatic effects of an initial dose of naproxen sodium 550 mg, followed by 275 mg of naproxen sodium prn, compared to placebo control in patients with clinically significant fever due to an upper respiratory illness with flu-like symptoms of viral origin.

Technical Approach:

Progress: Data was collected on 30 patients and referred to Syntex Labs. This study was part of a large, multi-institutional study conducted for the FDA by Syntex Labs. Records of the 30 patients are on file in CIS office. Study completed July 83.

Detail Summary Sheet

Date 30 Sep 83	Prot No.: 83-42	Status: Ongoing
Title: Skinfold Measurements and the Percentage of Body Fat Differences Between Black and Caucasian Male Soldiers.		
Start Date:	Est Comp Date: Dec 83	
Principal Investigator(s) Karen P. Hobson, MAJ, AMSC	Facility: USA MEDDAC, Ft Benning, GA	
Dept/Svc: Nutrition Clinic	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To 1) determine if there is a significant difference between the skinfold measurements taken on Black soldiers as compared to Caucasian soldiers; 2) determine the need for a race-specific standard of body fat percentage to be used in the evaluation of overweight soldiers; 3) evaluate the age factor differences in body fat percentage in the older age groups.

Technical Approach: One-time skin fold measurements of 500+ male soldiers.

Progress: Skinfold measurements have been taken on 450 soldiers (450 whites, 170 blacks, 46 others). Computer analysis for significant differences between the races will be accomplished in Oct 83.

Detail Summary Sheet

Date 1 Nov 83 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: Oct 81	Est Comp Date:
Principal Investigator(s) Donald A. Schlomer, M.D., CPT, MC	Facility: USA MEDDAC, Ft Campbell, KY
Dept/Svc: Surgery/Ophthalmology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: To provide to cataract patients the latest development in ophthalmology concerning the correction of aphakia vision.

Technical Approach: An intracapsular cataract extraction was performed followed by insertion of a Tennant Anterior Chamber Intraocular Lens.

Progress: FY 82 14 patients. Investigator PCS'd without submitting final report. Efforts to locate him were unsuccessful.

Detail Summary Sheet

Date 18 Oct 83	Prot No.: 83-29	Status: Ongoing
Title: Study of the Relationship Between Ambient, Personal, Expired Air Samples and Carboxyhemoglobin Levels Among Personnel Intermittently Exposed to Carbon Monoxide.		
Start Date: May 83	Est Comp Date:	
Principal Investigator(s) Jory S. Simmons, M.D. Larry C. Brantley	Facility: USA MEDDAC Ft Campbell, KY	
Dept/Svc: Preventive Medicine Activity	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine 1) if expired air serves as an accurate measure of blood carboxyhemoglobin levels; 2) if there is a difference in the measurement of carboxyhemoglobin levels and carbon monoxide expired levels between smokers and non-smokers; 3) if there is a significant relationship between expired breath, personal air samples, and ambient air samples.

Technical Approach: Determination of ambient air and expired breath samples using a calibrated Ecolyzer carbon monoxide instrument. Laboratory analysis of carboxyhemoglobin by Co-Oximeter. •

Progress: To date, two industrial operations have been utilized in this study. Six subjects have participated from a warehousing operation and five subjects have participated from a vehicle maintenance operation. Further investigations are pending the return of Dr. Simmons from TDY.

Detail Summary Sheet

Date 18 Oct 83		Prot No.: 78-14		Status: Ongoing	
Title: Intraocular Lens Study.					
Start Date: Jul 81			Est Comp Date:		
Principal Investigator(s) Norman T. Byers, M.D., LTC, MC			Facility: USA MEDDAC, Ft Jackson, SC		
Dept/Svc: Surgery/Ophthalmology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Mar 83 Review Results Continue	
Study Objective: Insertion in selected patients of Tennant Anterior Chamber Anchor Lens.					

Technical Approach: Using routine intracapsular cataract techniques, the lens would be inserted prior to final closure of the wound.

Progress: Prior number of subjects: 20. 34 patients have had intraocular implants in FY 83. All lenses were of the Tennant Anchor Anterior Chamber Lens Variety. Two patients had vitreous hemorrhage post-surgery, but have since done well.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 82-22 Status: Completed
 Title: Infant Rotavirus Diarrhea Study.

Start Date: Dec 81	Est Comp Date:
Principal Investigator(s) Christopher B. White, M.D., CPT, MC	Facility: USA MEDDAC, Ft Jackson, SC
Dept/Svc: Pediatrics	Associate Investigators: James J. Gibson, M.D., DAC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To identify epidemiologic characteristics of infant diarrhea caused by the rotavirus.

Technical Approach: Children less than 48 months of age with gastroenteritis were enrolled in this study. Age matched controls were also enrolled. Children studied were characterized by a questionnaire and had a stool specimen studied for rotavirus by ELISA testing and the feces were also cultured for bacterial pathogens.

Progress: Total of 121 children enrolled: 76 cases of acute gastroenteritis, and 45 control children entering with other complaints (matched to cases by sex, race, and six-month age group). No subject injuries or complaints resulted from the study.

Our findings were that about 25% of the cases of acute gastroenteritis could be attributed to the rotavirus, that there was strong seasonal variation, that our enzyme immunoassay test for detecting rotavirus in stool was specific and sensitive when compared to electron microscopy, and that cases of rotavirus gastroenteritis had the clinical characteristics that have been described in other studies of disease caused by this organism. In addition, and of greatest interest, the epidemiologic sources of acquisition of rotavirus infection appeared to be significantly different from characteristics of non-rotavirus gastroenteritis cases. Our study supported the hypothesis of acquisition of rotavirus infection by preschool age infants and toddlers from their parents, who had had a mild nonspecific gastroenteritis in the preceding week or two, and not from other school-age or preschool-age siblings, as has been more often hypothesized. Since effective immunization for the rotavirus has not yet been established, control of transmission is the only effective preventive measure we have available, and these data have important implications for effective prevention of transmission of the rotavirus to young children.

Study data were reported in June 1983 at the National Meeting of the Society for Epidemiologic Research in Winnipeg, Canada.

Two papers have been written and will submit to J Health Lab Sci and Am J Diseases Children.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 78-14 Status: Ongoing
 Title: Intraocular Lens Study.

Start Date: Oct 80		Est Comp Date:
Principal Investigator(s) Jimmy Carter, M.D., LTC, MC		Facility: USA MEDDAC, Ft Rucker, AL
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words: Intraocular Lens Aphakia Implant Surgery Ophthalmology		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: The objective of the ongoing FDA study is to determine the safety of the intraocular lens implant in the human eye.

Technical Approach: In all primary implants during this period, the extracapsular cataract approach was used. A style 20 posterior chamber lens manufactured by Surgidev Corporation was placed in the posterior chamber. In all secondary implants, the style 10 anterior chamber lens, by Surgidev Corporation, was used.

Progress: Patients thru FY 82: 47; FY 83 - 56. During this investigation period, 51 posterior chamber and five anterior chamber lenses were implanted. No eyes were lost at surgery or in the subsequent postop period. There was no pseudophakic bullous keratopathy sufficient to necessitate a corneal transplant. Opacification of the posterior lens capsule is certainly a progressive problem, but during the first year 10% only need a discission of the capsule. Approximately $\frac{1}{2}$ of all ECCE's are expected to need discission over the next five years. There were no retinal detachments in patients operated during this period. The incidence of persistent cystoid macular edema reducing functional vision to less than 20/40 was 4%. In three patients, pre-existing diabetic retinopathy reduced the final visual acuity; and, in two patients, a pre-existing macular scar reduced the final visual acuity.

In summary, this was a period wherein proven techniques were used with excellent success. Minimal complications were encountered.

Detail Summary Sheet

Date 1 Nov 83 Prot No.: 78-14 Status: Ongoing
Title: Intraocular Lens Study.

Start Date: Oct 82	Est Comp Date:
Principal Investigator(s) Ruben Orillac, M.D.	Facility: USA MEDDAC Panama
Dept/Svc: Surgery/Ophthalmology	Associate Investigators: Jerry D. Harrell, M.D., COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: Implantation of intraocular lenses in accordance with previously established FDA protocol.

Technical Approach: Currently accepted surgical techniques for cataract extraction and intraocular lens implantation using the operating microscope.

Progress: Prior implants 18. FY 83 - 20 implants. There were no complications or adverse effects.

Detail Summary Sheet

Date 18 Oct 83 Prot No.: 81-39 Status: Terminated
 Title: Long-term Suppression of Atrophie Blanche With Use of Phenformin.

Start Date: Sep 81	Est Comp Date:
Principal Investigator(s) Robert B. Blumer, M.D., COL, MC	Facility: USA MEDOAC Panama
Dept/Svc: Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To continue to suppress Atrophie Blanche in a patient placed and controlled on Phenformin and Ethylestrenol therapy since September 1972.

Technical Approach: Only one patient will comprise the investigation. The patient is selected because of well documented medical history of the disease Atrophie Blanche to include publication of the circumstances and treatment of this specific case in Archives of Dermatology, Vol 109, May 1974, pages 664-666 (Case 5). Additionally, the treatment regimen to be employed has been successfully ongoing since 1972.

Progress: This was a one-patient protocol. The patient was medically evacuated to Walter Reed Army Medical Center in Sep 82, and has not been seen in Panama since. Therefore, the protocol can be considered closed.

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